NIALL P. McCARTHY (admitted *Pro Hac Vice*)
nmccarthy@cpmlegal.com
JUSTIN T. BERGER (admitted *Pro Hac Vice*)
jberger@cpmlegal.com
ERIC J. BUESCHER (admitted *Pro Hac Vice*)
ebuescher@cpmlegal.com
MALLORY A. BARR
mbarr@cpmlegal.com
COTCHETT, PITRE & McCARTHY, LLP
San Francisco Airport Office Center
840 Malcolm Road
Burlingame, CA 94010
Telephone: (650) 697-6000
Facsimile: (650) 697-0577

JEFFREY W. STEIDLEY (SBN 19126300)
jeff@texlaw.us
THE STEIDLEY LAW FIRM
3701 Kirby Drive, Suite 1170
Houston, TX 77098
Telephone: (713) 523-9595
Facsimile: (713) 523-9578

Attorneys for Relator

UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF TEXAS

SHERMAN DIVISION

UNITED STATES OF AMERICA; STATE OF CALIFORNIA; STATE OF GEORGIA; COMMONWEALTH OF MASSACHUSETTS ex rel. [FILED UNDER SEAL], Plaintiffs, v. [FILED UNDER SEAL], Defendants.	CASE. NO 4:16-cv-547 **SECOND AMENDED COMPLAINT FOR MONEY DAMAGES AND CIVIL PENALTIES FOR VIOLATIONS OF THE FALSE CLAIMS ACT** **DEMAND FOR JURY TRIAL** **[FILED IN CAMERA AND UNDER SEAL PURSUANT TO 31 U.S.C. § 3730(b)(2)]**

NIALL P. McCARTHY (admitted *Pro Hac Vice*)
nmccarthy@cpmlegal.com
JUSTIN T. BERGER (admitted *Pro Hac Vice*)
jberger@cpmlegal.com
ERIC J. BUESCHER (admitted *Pro Hac Vice*)
ebuescher@cpmlegal.com
MALLORY A. BARR
mbarr@cpmlegal.com
COTCHETT, PITRE & McCARTHY, LLP
San Francisco Airport Office Center
840 Malcolm Road
Burlingame, CA 94010
Telephone: (650) 697-6000
Facsimile: (650) 697-0577

JEFFREY W. STEIDLEY (SBN 19126300)
jeff@texlaw.us
THE STEIDLEY LAW FIRM
3701 Kirby Drive, Suite 1170
Houston, TX 77098
Telephone: (713) 523-9595
Facsimile: (713) 523-9578

Attorneys for Relator STF, LLC

UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF TEXAS

SHERMAN DIVISION

UNITED STATES OF AMERICA; STATE OF CALIFORNIA; STATE OF GEORGIA; COMMONWEALTH OF MASSACHUSETTS ex rel. STF, LLC, an organization, Plaintiffs, v. TRUE HEALTH DIAGNOSTICS, LLC, a Texas corporation; CHRIS GROTTENTHALER, CEO & FOUNDER, an individual; CAROL NELLIS, an individual; KEVIN CARRIER, d/b/a MRT HEALTH CONSULTANTS LLC, an Alabama limited liability corporation; SAM FILLINGANE, DO, an individual; JEFFREY "BOOMER" CORNWELL, an individual; CHARLES MAIMONE, an individual, Defendants.	CASE NO. 4:16-cv-547 **SECOND AMENDED COMPLAINT FOR MONEY DAMAGES AND CIVIL PENALTIES FOR VIOLATIONS OF THE FALSE CLAIMS ACT** **DEMAND FOR JURY TRIAL** **[FILED IN CAMERA AND UNDER SEAL PURSUANT TO 31 U.S.C. § 3730(b)(2)]**

TABLE OF CONTENTS

PAGE No.

Plaintiffs UNITED STATES OF AMERICA ("United States"), STATE OF CALIFORNIA ("California"), STATE OF GEORGIA ("Georgia"), and COMMONWEALTH OF MASSACHUSETTS ("Massachusetts") by and through Relator STF, LLC, allege as follows:

I. INTRODUCTION

1. Over the past several years, TRUE HEALTH DIAGNOSTICS, LLC ("TRUE HEALTH"), and its owners, executives, and board members (collectively, "Defendants"), have perpetrated a multi-million dollar fraud on U.S. taxpayers through various schemes designed to defraud Medicare, Medicaid, and private insurers.

2. Defendants provide illegal kickbacks in several forms to doctors and clinics, to induce those doctors and clinics to refer Medicare, Medicaid, and private insurance business to them. The kickbacks take the following forms, as described in detail in this Complaint:

a. Defendants promise doctors they will never collect co-payments or patient deductible payments from the doctors' patients. This is of great benefit to the doctors, who are able to attract and retain patients' business by promising free lab testing. In exchange for this benefit, the doctors order large Cardiovascular Disease ("CVD") test panels from Defendants, including panels for Medicare beneficiaries. The large CVD test panels are designed by TRUE HEALTH. As such, the waiver of deductibles and co-payments constitutes illegal remuneration, designed by Defendants to "pull-through" higher-paying Medicare and other business to Defendants. Defendants tell physicians that there is no reason not to order these large panels because their patients will never have to pay anything. Furthermore, waiving insurance deductible and co-payments is explicitly illegal under the laws of several states. These large panels are ordered as often as four times a year and are among the most expensive test panels ever designed.

b. Defendants pay doctors inflated monthly "consulting" fees for discussing test results over the phone. The fees Defendants pay far exceed the fair market value of the consultations, and constitute illegal remuneration designed to induce the referral of Medicare, Medicaid, and other business.

c. Defendants contract with a sales force of independent contractors who are paid predominantly on commissions based on referrals of patients and are highly incentivized to increase referral business. Defendants enter into sales agreements to pay these independent contractors a commission based on a percentage of the laboratory's revenue in exchange for the contractor arranging for and recommending physicians who order tests that are reimbursed by federal programs. Anti-kickback statutes prohibit entities and individuals from receiving remuneration in return for "arranging for" or "recommending" the purchase or order of a "good" or "service" reimbursed by federal health programs. 42 U.S.C. §1320a-7b(b)(1)(B). The anti-kickback statutes likewise prohibit laboratories from paying such remuneration. *Id*.

d. Defendants pay doctors to be members of their "Speakers Bureau," in exchange for the doctors' referral of all CVD panels – including panels for Medicare and Medicaid beneficiaries – to Defendants.

3. These practices constitute illegal kickback schemes, no more legal than if Defendants simply handed doctors envelopes of cash in exchange for Medicare, Medicaid, and other referrals.

4. Additionally, Defendants systematically bill Medicare, Medicaid, and other payors for medically unnecessary tests. Specifically, Defendants' test bundles ("panels") include tests that are pre-selected by Defendants as part of their panels; TRUE HEALTH sales representatives encourage doctors not to de-select any of the tests. Because TRUE HEALTH does not bill patients for co-pays or deductibles, the physicians have no incentive to de-select any of the tests. Because there is no cost to their patients, TRUE HEALTH's physician clients order TRUE HEALTH's test panels indiscriminately for the vast majority of their patients without any thought or consideration of medical necessity. Knowing this, TRUE HEALTH has designed its test panels to maximize reimbursement from Medicare and other payors. Defendants then perform and bill Medicare and other payors for each of the tests. Each time they do so, Defendants violate the Federal False Claims Act and the Georgia, and Massachusetts' false claims acts.

5. Defendants have also engaged in a new, equally fraudulent "pass-through" billing scheme. TRUE HEALTH routes its testing through small hospitals to generate inflated payments,

often seventy percent (70%) more profit for the exact same tests because of different reimbursement rates between hospitals and commercial laboratories, and between in-network and out-of-network providers. This new scheme, commonly referred to as a "Hospital Outpatient Department," or "HOPD," is fraudulent on at least two levels: (1) the hospitals submit falsified claims for reimbursement under their NPI number for laboratory testing not performed at the hospital in exchange for (2) a portion of the reimbursement amount, which is an illegal kickback. Each time Defendants perform and bill Medicare and other payors for these tests, Defendants violate the Federal False Claims Act and the California Insurance Fraud Prevention Act.

6. Defendant TRUE HEALTH acquired Health Diagnostic Laboratory, Inc. ("HDL") in September 2015. By acquiring HDL, TRUE HEALTH has increased its Medicare, Medicaid, and private insurance business significantly, thereby increasing the magnitude of its fraudulent practices.

7. A member of Relator recently received an email from a California physician confirming that TRUE HEALTH perpetrates the fraudulent schemes alleged above.

8. In the email (attached hereto as Exhibit 1) the physician explains that a TRUE HEALTH representative she recently spoke with confirmed: (1) TRUE HEALTH requires that physicians use the large test panels, which consist of medically unnecessary lab tests; (2) these large panels should be run every three months if any of the patient's initial tests establish any abnormalities; (3) about 95% of TRUE HEALTH's client physicians utilize these medically unnecessary panels; (4) TRUE HEALTH will not charge privately insured patients co-pays or deductibles; (5) TRUE HEALTH will use their client physicians' phlebotomists to draw blood, treating them as independent contractors and paying them $15 per blood draw; (6) TRUE HEALTH directs its physician clients to have their phlebotomists' "clock-out" while they draw blood for TRUE HEALTH submissions, and encourages the physicians to reduce the phlebotomists salaries by the amount TRUE HEALTH pays the phlebotomists for blood draws; and (7) TRUE HEALTH would provide a free health coach to work with physicians' patients.

9. TRUE HEALTH's CEO, CHRIS GROTTENTHALER, issued a letter to physicians assuring them that TRUE HEALTH's acquisition of HDL would not disrupt the flow of kickbacks from TRUE HEALTH to its physician clientele. Specifically, Defendant Grottenhaler assured TRUE

HEALTH's clients that things would continue to be "**business as usual**." (See September 30, 2015 letter from CHRIS GROTTENHALER to Providers, attached hereto as Exhibit 2). Defendant Grottenthaler has made it clear that TRUE HEALTH is intent on defrauding Medicare and other payors through the various schemes noted above and described in the physician email attached hereto as Exhibit 1.

10. Additionally, despite certifying compliance with various federal statutes, Defendants have knowingly misrepresented their laboratory's operations. Prior to the acquisition of HDL, Defendants "sent out" more than 30% of their tests to other laboratories, yet billed Medicare as if they had processed the tests themselves. This is illegal.

11. These schemes violate not only Medicare regulations, but also state Medicaid and insurance regulations. The fraudulent intent of these schemes is exacerbated by Defendants knowingly charging state Medicaid programs at rates far in excess of their lowest charges. Defendant TRUE HEALTH charges various state Medicaid programs as much as 100% more for lab tests than it does its private insurers. As shown in Exhibits 3 and 4, a survey of billing for 29 TRUE HEALTH tests, which amounts to 31% of TRUE HEALTH's 85 test Baseline Panel, shows that on average Defendants overcharged Medicaid programs in Georgia by 62%, and Massachusetts by 51% (See Medicaid Lowest Charge charts, attached hereto as Exhibits 3, and 4 respectively).

12. TRUE HEALTH's schemes have allowed it to secure substantial Medicare and other business in a short period of time. TRUE HEALTH's success would be unattainable without its fraudulent schemes because TRUE HEALTH has zero proprietary or otherwise unique testing to offer.

13. Medicare is administered by the United States government, and provides health coverage to people 65 years of age and older. Medicare's soaring costs are staggering. In 2014, Medicare expenditures accounted for $511 billion of federal spending. Knowing that the federal Government lacks the ability to track the massive amount of Medicare money as it flows through the complex healthcare delivery system, unscrupulous companies see government money as an easy source for padding their profits. Sadly, Defendants have become part of this problem through their

abuse of the Medicare program – a program designed to benefit senior citizens, not private companies.

14. Title XIX of the Social Security Act and Title 42 of the Code of Federal Regulations authorize individual states to develop and manage their own Medicaid programs. Medicaid is a joint federal-state program that provides health care benefits, including laboratory services coverage, for certain groups including the poor and disabled. The funding for Medicaid is shared between the federal and state governments. Each state is required to implement a state plan containing certain specified minimum criteria for coverage and payment of claims in order to qualify for federal funds for Medicaid expenditures. 42 U.S.C. § 1396a. The federal Medicaid statute sets forth the minimum requirements for state Medicaid programs to qualify for federal funding. *Id*. The federal portion of each state's Medicaid payments, known as the Federal Medicaid Assistance Percentage is based on a state's per capita income compared to the national average. 42 U.S.C. § 1396d (b).

15. In addition to the Medicaid statutes, many states also have their own false claims statutes, which mirror the federal FCA. Defendants' schemes violate these state statutes as well. These violations are even more egregious because they have been accomplished through knowing violations of the long-established federal anti-kickback laws.

16. Defendants' illegal schemes make health care more complicated and more expensive than is should be to extract money to which they were not entitiled. Their schemes have defrauded taxpayers and are detrimental to the American health care system because they offer no benefit to patients, health care markets, or society at-large. In engaging in these illegal practices, Defendants are not only cheating the system, but also driving competitors out of the marketplace, thereby reducing the quantity and quality of treatment options for the poor, the elderly, and the disabled.

17. This is a *qui tam* action for violation of the federal False Claims Act (31 U.S.C. §§ 3150 *et seq*.) and the false claims acts of Georgia and Massachusetts to recover treble damages, civil penalties and attorneys' fees and costs for Plaintiffs and on behalf of the United States, Georgia, and Massachusetts for fraudulent Medicare and Medicaid billings. Non-public information personally known to Relator STF, LLC ("STF") serves as the basis for this action. Some of Defendants' schemes have also caused private insurers in California to be overcharged. Accordingly, Relator

brings claims under California Insurance Code §1871.7, *et seq*., to recover fraudulent charges on behalf of the California Department of Insurance.

II. JURISDICTION AND VENUE

18. This Court has jurisdiction over this action pursuant to 31 U.S.C. sections 3730(b) and 3732(a), which confer jurisdiction on this Court for actions brought under the federal False Claims Act, and authorize nationwide service of process. Venue is proper in this district pursuant to 31 U.S.C. section 3732(a), as all Defendants transact business in the Eastern District of Texas.

III. PARTIES

19. The plaintiffs in this action are the UNITED STATES OF AMERICA ("United States"), the STATE OF CALIFORNIA ("California"), the STATE OF GEORGIA ("Georgia"), and the COMMONWEALTH OF MASSACHUSETTS ("Massachusetts") by and through Relator STF, LLC.

20. Relator STF, LLC is a limited liability company, whose members are involved in the laboratory industry.

21. Defendant TRUE HEALTH DIAGNOSTICS, LLC ("TRUE HEALTH"), is a Texas limited liability company with its principal place of business in Frisco, TX. In September 2015, TRUE HEALTH bought Health Diagnostics Laboratory, Inc. (""HDL"), a Richmond, Virginia-based company, through a bankruptcy proceeding.

22. Defendant CHRIS GROTTENTHALER is CEO and founder of Defendant TRUE HEALTH. This is not the first time Defendant Grottenhaler has been connected to an illegal scheme to bribe physicians for the purpose of capturing Medicare business. Defendant Grottenhaler was previously VP of Finance at Ameritox. During Defendant Grottenhaler's tenure at Amertiox, the Department of Health and Human Services accused the company of paying kickbacks to induce its physician clientele to refer drug testing services to the lab that were reimbursable by Medicare. In 2010 Ameritox paid $16.3 million to settle the case. TRUE HEALTH's business model is essentially the same as Ameritox's fraudulent business model: pay physicians cash to induce Medicare referrals. At Defendant Grottenhaler's direction, however, TRUE HEALTH adds a new twist. TRUE HEALTH pays physicians' phlebotomists at above market rates for blood draws that are submitted to

TRUE HEALTH for test panels. The additional income the physicians' phlebotomists generate from TRUE HEALTH allows physicians to reduce their phlebotomists' salaries, thereby increasing the physicians' profits. TRUE HEALTH does this to induce Medicare referrals.

23. Defendant CAROL NELLIS is Senior Vice President of Sales and Marketing at TRUE HEALTH. Defendant Nellis worked with Defendant Grottenhaler at Ameritox during the fraud described above. During a conference in Miami, Defendant Nellis and Defendant KEVIN CARRIER personally assured a physician that TRUE HEALTH would not charge her patients co-pays or deductibles. Specifically, Defendants Nellis and Carrier assured the physician that she "should not worry as they (TRUE HEALTH) never actually required that patients pay anything. [She] therefore would not be concerned about the cost to patients." (See 9-22-15 email attached hereto as Exhibit 5).

24. Defendant SAM FILLINGANE, D.O., is Chair and Director of Medical Education at TRUE HEALTH. Defendant Fillingane leads TRUE HEALTH's kickback scheme for Medicare referrals by dispensing cash to physician clients for a monthly phone conversation with him. Defendant Fillingane was previously the highest paid physician on HDL's list of doctors receiving money from Medicare as a result of referring business to HDL. Defendant Fillingane refers a considerable amount of Medicare, Medicaid, and other government funded healthcare business to TRUE HEALTH. TRUE HEALTH pays Defendant Fillingane to influence other physicians to refer Medicare, Medicaid, and other government funded healthcare business to TRUE HEALTH.

25. Defendant KEVIN CARRIER, through his wholly owned LLC, MRT HEALTH CONSULTANTS, became a contract sales representative for TRUE HEALTH in 2014. On May 10, 2015, Defendant Carrier sent an email to the physician mentioned above, stating the following:

> True Health Diagnostics is a value based lab, meaning we intend to deliver ninety-five percent of the clinical value at half-costs. Our intention at True Health Diagnostics is to protect the provider and the patient by delivering high value testing while at the same time minimizing, if not eliminating unnecessary investigational testing. We believe by doing this we can provide a high level of care to the patient without exposing the patient to unreasonable bills nor exposing the provider to extensive scrutiny by payors.

(See 5-10-15 email, attached hereto as Exhibit 5). These assurances were patently false. First, TRUE HEALTH does not provide CVD test panels at half cost. Instead, the TRUE HEALTH Baseline

Panel has 85 tests at a Medicare cost of at least $2,000. Second, the TRUE HEALTH Baseline Panel has at least eight tests that the FDA has not approved. Defendant Carrier, along with Defendant Nellis, told that same physician during a meeting in Miami that the physician "should not worry as they (True Health) never actually required that patients pay anything." (9-22-15 email attached hereto as Exhibit 5).

26. Defendant JEFFREY P. "BOOMER" CORNWELL is a sales representative for Defendant TRUE HEALTH. Defendant Cornwell is based in Texas. Defendant Cornwell was previously a contract sales representative for Blue Wave.

27. Defendant CHARLES MAIMONE is a contract sales representative for Defendant TRUE HEALTH. Defendant Maimone is based in New Jersey. Defendant Maimone was previously a contract sales representative for Blue Wave.

28. Other shareholders, officers, and board members of Defendants controlled and profited from the schemes alleged herein, and this complaint will be amended with their names once they are known.

IV. OVERVIEW OF THE SCHEME

29. TRUE HEALTH is a commercial reference laboratory. Commercial reference laboratories perform clinical laboratory services, which entail analyses of human body specimens, including blood, to assist physicians in diagnosing human disease and monitoring treatment. TRUE HEALTH performs clinical laboratory services for patients covered under the federal Medicare program, state Medicaid programs, and private managed care companies. Commercial reference laboratories, like TRUE HEALTH, obtain requests for clinical tests from physicians, clinics, and hospitals. When the laboratories run these tests, they submit claims for reimbursement to the appropriate payer – Medicare, Medicaid, or private insurance – for reimbursement, identifying the tests performed by a uniform Current Procedure Technology ("CPT") code. These claims are typically submitted electronically to government and private payors such as Aetna, Cigna, Blue Cross/Blue Shield, and United Healthcare.

30. As a condition of receiving payment from Medicare and Medicaid, TRUE HEALTH certified, both implicitly and explicitly, its compliance with relevant federal and state statutes and

regulations, as more fully described herein, including attesting that the laboratory is not violating the Anti-Kickback statutes on all claims. Rather than abide by these statutes and regulations, Defendants defrauded these programs, induced physicians to order tests by offering kickbacks, and submitted claims for medically unnecessary tests.

31. Despite certifying compliance with relevant Medicare statutes, Defendants have misrepresented their laboratory operations, in violation of federal statutes. Specifically, prior to acquiring HDL, Defendants have "sent out" more than 30 percent of their lab tests to other laboratories. Defendants need to do this because they did not have the capabilities, equipment, or staff to perform the tests they offer. Nonetheless, Defendants falsely certify that the tests were performed at their laboratory in order to submit claims to Medicare. In violation of express CLIA requirements, Defendants also omit, from their test reports, the identity of the lab that actually performed the tests. Defendants' failure to identify the laboratory performing the tests and its Medical Director is a serious violation of CLIA requirements.

32. In order to capture and retain Medicare and Medicaid business, Defendants also offer several forms of illegal remuneration to physician customers in order to induce referral of Medicare and Medicaid business.

33. First, Defendants waive patients' private insurance deductible payments. Most private insurance companies require that a patient ordering a laboratory test make a deductible payment to the laboratory until the patient has met his or her deductible amount each year. The deductible payments can be significant to patients. For example, for a TRUE HEALTH Baseline Panel, the deductible payment, if charged, could be more than $2,000. Accordingly, the waiver of a deductible payment is a significant benefit that a physician can provide to his or her patients. Knowing this, Defendants promise physicians that they will not collect deductible payments, as long as the physicians send all of their CVD-related business—including Medicare and Medicaid business—to Defendants' laboratories.

34. Defendants also waive patients' private insurance co-payments. A significant portion of a physician's non-Medicare patients will be covered by private insurance. Most private insurance companies require that a patient ordering a laboratory test make a co-payment of approximately 20

percent of allowable charges to the laboratory. The co-payments can be significant to patients, especially those being treated with satin therapy, who require regular medical treatment and lipid testing with attendant co-payments at least four times per year. For example, in the case of the TRUE HEALTH Baseline panel, the co-payment, if charged, could be at least $400. Accordingly, the waiver of a co-payment is a significant benefit that a physician can provide to his or her patients. Knowing this, Defendants promise physicians that they will not collect co-payments, as long as the physicians send all of their CVD-related business—including Medicare and Medicaid business—to Defendants' laboratories.

35. Nearly half of individuals in the United States do not have the liquidity to pay an unexpected $400 expense without taking on debt. Board of Governors of the Federal Reserve System, "Report on the Economic Well-Being of U.S. Household in 2015," (May 2016) at p. 1, available at https://www.federalreserve.gov/2015-report-economic-well-being-us-households-201605.pdf. In light of this reality, out-of-pocket medical expenses in particular are a concern for many Americans. *See id.* at pp. 24-25. Deductibles and co-payments can be financially devastating to a large share of the population. As such, waiver of them is attractive for doctors who do not want to field questions from patients about why they are being saddled with an unexpected medical bill for laboratory tests. Yet, these deductibles and co-payments function as an economic restraint on doctors from ordering unnecessary and duplicative laboratory tests.

36. Though Defendants lose money on uncollected co-payments and deductibles, they more than make up the difference with the profits they earn on the Medicare and Medicaid referral business. This Medicare and Medicaid business, induced by the deductible and co-payment waiver for privately insured patients, is referred to in the industry as "pull-through" business. The majority of Medicare patients are receiving statin therapy, and therefore receive lipid testing four times per year. This amounts to annual Medicare payments of over $8,000 per patient.

37. Waiving co-payments and deductibles in this manner, to induce the referral of pull-through Medicare and Medicaid business constitutes illegal inducement, strictly prohibited by the anti-kickback laws.

38. The second form of illegal remuneration Defendants provide to induce the referral of Medicare and Medicaid business is the payment to physicians of inflated "consulting" fees. When a physician orders a test for a patient, the laboratory can call and discuss the results of the tests with the physician. Defendants in this case pay physicians grossly inflated "consulting" fees for mere minutes of discussing lab results with the ordering physicians. These "consulting" fees are pure artifice, thinly disguised kickbacks. The former Blue Wave Sales Reps designed this scheme as a replacement for the bribes they previously paid for "packaging fees." The fees paid by Defendants far exceed the fair market value of the physicians' time, and are intended as illegal remuneration to induce the referral of physicians' Medicare, Medicaid, and other business.

39. The third form of kickbacks Defendants pay are "speaking fees" paid to physicians who sign up to be part of Defendants' "Speakers Bureau." In exchange for speaking at conferences once or twice a year, if at all, and/or local dinners and round tables, Defendants pay these referring physicians thousands of dollars. Again, the fees Defendants pay far exceed the fair market value of the physicians' speaking services, and are intended as illegal remuneration to induce the referral of the physicians' Medicare, Medicaid, and other business.

40. The fourth form of kickbacks is in Defendants' agreements with non-employee sales persons responsible for delivering TRUE HEALTH's test volume. Defendants enter into sales agreements whereby TRUE HEALTH pays contractors a commission based on a percentage of the laboratory's revenue in exchange for the contractor arranging for and recommending physicians who order tests that are reimbursed by federal programs. Anti-kickback statutes prohibit entities and individual s from receiving remuneration in return for "arranging for" or "recommending" the purchase or order of any "good" or "service" reimbursed by federal health programs. 42 U.S.C. §1320a-7b(b)(1)(B). The anti-kickback statutes likewise prohibit TRUE HEALTH from paying such remuneration. Id. Defendants negotiated and entered into these agreements, knowing they violated anti-kickback statutes and, therefore, submitted false claims.

41. In addition to providing illegal kickbacks, Defendants overcharge Medicare, Medicaid, and other government programs by systematically billing for medically unnecessary tests. As just one of many examples, two of TRUE HEALTH's test bundles ("panels") include both an Apo

B test, and an LDL-P test. Both of these tests measure total LDL particles. There is no medical benefit to including both of these tests since they provide the same medical information and treatment would not be affected by including both tests. Defendants pre-select both tests as part of their panels; doctors are encouraged not to de-select one of the tests. Defendants then perform, and bill Medicare, Medicaid, and other government programs for, each of the tests. Defendants charge Medicare, Medicaid, and other government programs in excess of $19.95 for the Apo B test, and $42.93 for the LDL-P test. Each time they do so, Defendants violate the False Claims Act.

V. DEFENDANTS KNOWINGLY VIOLATED THE FEDERAL FALSE CLAIMS ACT BY MISREPRESENTING THEIR COMPLIANCE WITH BASIC LABORATORY OPERATIONS REGULATIONS.

A. Defendants outsource laboratory work in excess of the thirty percent permitted by the "shell laboratory provision" requirements.

42. Prior to acquiring HDL, Defendants knowingly violated the False Claims Act by referring more than 30 percent of their lab tests to one or more non-related laboratories (i.e., laboratories that Defendants do not wholly own) and then billing Medicare for those referred tests. Specifically, Social Security Act section 1833(h)(5)(A) provides that a referring laboratory may bill for clinical laboratory diagnostic tests on the clinical laboratory fee schedule for Medicare beneficiaries performed by a reference laboratory only if the referring laboratory does not, inter alia, refer more than 30 percent of the clinical laboratory tests for which it receives requests for testing during the year. Defendants have routinely referred more than 30 percent of their lab tests to non-related labs and then billed Medicare for those tests in violation of the False Claims Act.

B. Defendants knowingly misrepresent their laboratory's operations in order to bill Medicare for tests it does not perform.

43. Defendants knowingly misrepresent to Medicare that they perform the majority of their tests in house. Federal law requires that lab test reports include information about the name and address of the laboratory performing the tests. 42 C.F.R. § 493.1291(c). As of at least August 2015, TRUE HEALTH did not have the capacity to perform the litany of tests included in its panels. TRUE HEALTH sent these tests out to other laboratories to perform or simply did not perform them at all.

Yet, TRUE HEALTH only lists its own laboratory on its "Laboratory Test Results Report." (See Exhibit 5).

44. Consequently, each test that TRUE HEALTH billed Medicare for but did not perform itself, and did not properly identify as a test performed by another laboratory, constitutes a violation of the False Claims Act.

VI. DEFENDANTS KNOWINGLY VIOLATED THE FEDERAL FALSE CLAIMS ACT THROUGH MULTIPLE ILLEGAL KICKBACK SCHEMES.

45. Defendants violated the False Claims Act by charging Medicare, Medicaid, and other government programs for lab tests that were referred to Defendants by providers because of kickbacks offered to those providers by Defendants. Defendants' practices are unlawful as kickback schemes, strictly prohibited by Medicare statutes. Specifically, 42 U.S.C. § 1320a-7b(b)(2)(A) prohibits "Illegal remunerations" for "[w]hoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) ***directly or indirectly, overtly or covertly***, in cash or in kind to any person to induce such person to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program . . . ." 42 U.S.C. § 1320a-7b(b)(2)(A) (emphasis added).

46. Interpretations of this language by the federal authorities provide useful guidance in applying these anti-kickback laws, and establish that Defendants have violated the anti-kickback laws of the United States through the conduct described herein. For example, the federal Department of Health and Human Services, Office of the Inspector General ("OIG"), reaffirmed on May 9, 2008, that: "[W]hen a laboratory offers or gives an item or service for free **or less than fair market value to a referral source, an inference arises that the item or service is offered to induce the referral of business**." OIG Advisory Opinion No. 08-06. An anti-kickback "violation arises if the discount whatever its size is **implicitly or explicitly tied** to referrals of" government-funded business. OIG Opinion Letter, April 26, 2000.

47. In October 1994, the OIG issued a Special Fraud Alert, entitled "How Does the Anti-Kickback Statute Relate to Arrangement for the Provision of Clinical Lab Services?" As an example

of a situation giving rise to an inference of an illegal kickback, the Special Fraud Alert cited laboratories that waive charges to providers for lab tests of managed care patients (such as the co-payments and deductibles of patients here).

48. Moreover, in June 2005, the OIG issued an Advisory Opinion concluding that payments by a laboratory to referring physicians of $6 per day for "collection of blood samples," likely constituted "prohibited remuneration under the anti-kickback statute." OIG Advisory Opinion No. 05-08, at pp. 1-2. Specifically, the OIG concluded that:

> **Where a laboratory pays a referring physician to perform blood draws, particularly where the amount paid is more than the laboratory receives in Medicare reimbursement, an inference arises that the compensation is paid as an inducement to the physician to refer patients to the laboratory . . . .**
>
> . . . . Because the physicians would receive a portion of the Lab's reimbursement for blood tests resulting from the physicians' referrals, **the physicians have a strong incentive to order more blood tests. As a result, there is a risk of overutilization and inappropriate higher costs to the Federal health care programs.**

Id. at p. 4.

49. More recently, the OIG issued and opinion stating that when a laboratory pays a referring physician for performing blood draws, and where the amount exceeds $3, "an inference arises that the compensation is paid as an inducement to the physician to refer patients to the laboratory." OIG Advisory Opinion No. 05-08, p. 4; *see also* OIG Special Fraud Alert: Laboratory Payments to Referring Physicians, p. 4, n.10 (June 2014).

50. Defendants violated the anti-kickback laws described in these OIG opinions by: (1) waiving co-payments and deductibles; (2) paying referring physicians inflated "consulting fees"; (3) paying physicians' phlebotomists $15 for "collection of blood sample" and encouraging the physicians to reduce their phlebotomists salaries by having them clock-out to draw patient specimens for TRUE HEALTH thereby increasing the physicians' profit; (4) contracting with sales persons on a 1099 basis; and (5) paying sham "Speakers Bureau" fees to referring physicians. All of these kickback schemes are both implicitly and explicitly tied to the referral of Medicare, Medicaid, and other government healthcare business and therefore violate the anti-kickback laws described in the aforementioned OIG opinions. Defendants presented to Medicare, Medicaid, and other government

programs claims for reimbursement of laboratory tests the referral of which was induced, in whole or in part, directly or indirectly, overtly or covertly, by the provision of the kickbacks described above. Each of those claims constitutes a violation of the False Claims Act.

51. At all times relevant hereto, Defendants knew that federal law prohibited their giving or receiving these kickbacks. Defendants certified, both explicitly and implicitly, that each claim they submitted to Medicare would fully comply with all statutes and regulations, including the anti-kickback provisions, and that as Medicare providers, they would comply with all pertinent statutes and regulations, including the anti-kickback provisions.

52. Each claim for payment that Defendants submitted to Medicare, Medicaid, and other government programs from at least 2014 to the present, that was referred to Defendants by a provider who received from Defendants any of the forms of remuneration described above constitutes a false claim in violation of the False Claims Act, 31 U.S.C. § 3729 *et seq.* Over this time period, Defendants have submitted hundreds of thousands of such claims for payments, and received tens, if not hundreds, of millions of dollars from the Government as a result of these illegal kickbacks.

A. Defendants' waiver of patient co-pay and deductibles are illegal kickbacks.

53. Defendants defrauded Medicare and private insurers by routinely waiving patients' deductibles or copays as incentive for physicians to refer business to TRUE HEALTH. TRUE HEALTH's Sales Representatives met with physicians and encouraged them to order panels for their non-Medicare and Medicare covered patients. In doing so, TRUE HEALTH promised to waive patients' private insurance co-payments and deductibles.

54. Typically, private insurance companies and some government healthcare programs require that a patient ordering a laboratory test make a co-payment of approximately 20% of allowable charges to the laboratory.

55. Private insurance companies may also require their patients to make a deductible payment to the laboratory until the patient has met his/her deductible amount for the year. Managed care companies, such as Blue Cross/Blue Shield of California, United Healthcare, Aetna, and Cigna, administer a variety of health and welfare benefit plans. As part of their fiduciary responsibilities to their plan members, managed care companies are responsible for controlling healthcare costs. One

way these companies control costs is by requiring plan members to pay deductibles and co-payments. These payment requirements safeguard the plan so that plan members and their physicians will not order excessive, unnecessary or duplicative tests for patients. As such, deductibles and co-payments act as embedded internal controls to ensure that unnecessary tests are not ordered.

56. In *Reynolds v. California Dental Service*, the California Court of Appeals upheld the validity of the ban against waiving copayments, writing: "The ban against waiving the copayment is simply the corollary of the rule that a [health care provider] must report his true fee to [the plan]; if a [health care provider] intends to waive the copayment, it is fraudulent for him to report to the [the plan] that his fee includes the copayment." 200 Cal. App. 3d 590, 602 (1988). This conduct is thus not a mere breach of contract between providers and insurers; it is fraud; fraud that leads to unnecessary medical testing, and ultimately, higher premiums for consumers.

57. In addition to California, other states have made clear the impropriety of waiving co-payments and deductibles. For example, the Florida Statutes provide, in pertinent part:

> (7)(a) **It shall constitute a material omission and insurance fraud,** punishable as provided in subsection (11), for any service provider, other than a hospital, to engage in a general business practice of billing amounts as its usual and customary charge, **if such provider has agreed with the insured or intends to waive deductibles or copayments, or does not for any other reason intend to collect the total amount of such charge.** With respect to a determination as to whether a service provider has engaged in such general business practice, consideration shall be given to evidence of whether the physician or other provider made a good faith attempt to collect such deductible or copayment.

Fla. Stat. § 817.234(7) (emphasis added).

58. Similarly, the Colorado Criminal Code prohibits "[b]usiness practices that have the effect of eliminating the need for actual payment by the recipient of health care of required copayments and deductibles in health benefit plans," for the stated reason "it has the effect of increasing health care costs by removing the incentive that copayments and deductibles create in making the consumer a cost-conscious purchaser of health care" Colorado Revised Statutes Title 18 Criminal Code § 18-13-119.

59. Under the Medicare program, "Routine waiver of deductibles and co-payments by charge-based providers, practitioners or suppliers is unlawful because it results in . . . false claims . . .

[and] excessive utilization of items and services paid for by Medicare. HHS OIG Special Fraud Alerts, available at https://oig.hhs.gov/fruad/docs/alertsandbulletins/121994.html (Dec. 19, 1994).

60. There can be no doubt that Defendants' waiver of co-payments and deductibles is well-known throughout the industry to be a prohibited practice.

61. One of the principal purposes behind co-payment and deductible requirements is to make patients conscious of the expense of their medical services, and thereby discourage the ordering and performance of unnecessary medical services. Co-payments and deductibles act as embedded internal controls for payors. There is no better mechanism to ensure that unnecessary tests are not ordered than requiring patients to pay a portion of the invoices for laboratory tests.

62. Although co-payments and deductibles can be a financial burden to patients, especially to those seeking treatment for coronary artery disease (which require expensive CVD panels), service providers are required to make all necessary efforts to collect co-payments from patients, with limited exceptions.

63. Accordingly, waivers of insurance co-payments and deductibles are significant benefits that physicians can provide to their patients because they allow the patients free laboratory testing no matter how many tests are ordered. Physicians therefore market these waivers to their patients to make their offices more appealing, thereby improving the physicians' overall revenue and ratings. These waivers save physicians from having to deal with patients upset over large deductible payments and co-payments for questionable laboratory tests. Ultimately, this mutually beneficial kickback arrangement incentivizes physicians to indiscriminately order all available tests and to do so strictly from TRUE HEALTH.

64. Knowing this, Defendants promise physicians that it will not collect co-payments or deductibles. For example, as part of its sales pitch, Defendants' sales representative in the Southeast told a physician that while TRUE HEALTH would bill private insurance companies and possible patients, TRUE HEALTH never required patients to pay. (See 9-22-15 email attached hereto as Exhibit 5). Defendant implicitly reiterated TRUE HEALTH'S co-pay and deductible waiver in a May 10, 2015 email to a physician stating: "[W]e can provide a high level of care to the patient **without exposing the patient to unreasonable bills nor exposing the provider to extensive**

scrutiny by payors." (See Exhibit 5) (emphasis added). Defendants' message is clear: physicians can order any test they want – even medically unnecessary tests – because the costs are picked up by Medicare, Medicaid, other government programs, and insurance companies. Although TRUE HEALTH lost money on uncollected co-payments and deductibles, it more than made up the difference with the profits it earned on the referral business.

65. While TRUE HEALTH's written billing policy claims to make "reasonable attempts" to collect from patients, in reality no effort is actually made to collect from patients. In fact, Defendants' sales force, including specifically TRUE HEALTH's VP of Sales and Marketing, CAROL NELLIS, and TRUE HEALTH sales representatives JEFFREY P. "BOOMER" CORNWELL out of Texas, KEVIN CARRIER out of Alabama, and CHARLES MAIMONE out of New Jersey , guarantee physicians that their patients would not receive a bill for their tests.

66. Waiving co-payments and deductibles in this manner, to induce physicians to order tests, constitutes illegal inducement, strictly prohibited by anti-kickback laws. *See* 42 U.S.C. §1320a-7a. As discussed above, anti-kickback statutes prohibit the knowing and willful remuneration (including discounts) even if one purpose of the remuneration is to induce or reward referrals of Federal health care program business. By engaging in this unlawful conduct, TRUE HEALTH also encouraged the submission of medically unreasonable and unnecessary tests, thereby violating 42 U.S.C. 1395y(a)(1)(A). As such, each of these claims constitutes a false claim in violation of the False Claims Act (31 U.S.C. § 3729 et seq.), and the California Insurance Code.

67. Defendants' waivers of co-payments and deductibles further undermine the private insurance companies' efforts to control healthcare costs. Defendants lure private insurance patients through misrepresenting the patients' responsibilities under their insurance plans, promising not to collect required payments, and promising not to seek reimbursement for any remaining portion of the patients' bills not covered by their insurance plan. In so doing, TRUE HEALTH increases the volume of its business while simultaneously increasing the damage to the private insurance companies.

/ / /

/ / /

B. Defendants' inflated "consulting fees" are illegal kickbacks.

68. Defendants induced the ordering of its tests – including tests ultimately billed to Medicare, Medicaid, and other government programs – by paying physicians significant amounts every month to review lab results over the phone. As a pretense, Defendants tell medical providers that the physician is providing "consulting services" to TRUE HEALTH.

69. In reality, Defendants' "consulting fees" are an unlawful kickback scheme, strictly prohibited by the Medicare statutes, and give rise to False Claims Act liability. The "consulting fees" paid by Defendants to referring providers in this case are no different from those proscribed by the OIG through its Advisory Opinions. Defendants' fees and other "compensation provides an obvious financial benefit to the referring physician, and it may be inferred that this benefit would be in exchange for referrals to the Lab." OIG Advisory Opinion No. 05-08, at p. 4. This alone gives rise to an inference of illegal remuneration.

70. Moreover, as in the scenario considered by the OIG's Advisory Opinion, the "consulting" fees and other remuneration provided by Defendants have the effect of incentivizing physicians to order more tests, creating a "risk of overutilization and inappropriate higher costs to the Federal health care programs." *See* OIG Advisory Opinion No. 05-08, p. 4.

71. Defendants presented to Medicare, Medicaid, and other government programs claims for reimbursement of laboratory tests which were neither reasonable nor necessary but were ordered by physicians in exchange for kickbacks. In doing so, Defendants caused hundreds of thousands of submissions of reimbursement claims for laboratory tests that were not medically necessary. As such, each of these claims constitutes a false claim in violation of the False Claims Act (31 U.S.C. §§ 3729 *et seq*.). Defendants certified, both explicitly and implicitly, that each claim they submitted to Medicare would fully comply with all statutes and regulations, and that as Medicare providers they would comply with all pertinent statutes and regulations.

C. Defendants' sham "Advisory Board" is an illegal kickback.

72. Similar to Defendants' fraudulent "consulting fees" scheme, Defendants also fraudulently paid doctors who allegedly participated on their sham "Advisory Board." Defendants paid high volume physicians to move their business to TRUE HEALTH in exchange for an "advisor"

fee. Defendant Dr. Sam Fillingane, TRUE HEALTH's Chair and Director of Medical Education, heads TRUE HEALTH's sham "Advisory Board." Dr. Fillingane moved his laboratory testing to TRUE HEALTH upon accepting this position. TRUE HEALTH's website makes only a passing reference to this Advisory Board, but no doctors are named.

73. Again, Defendants' practices are an unlawful kickback scheme, strictly prohibited by the Medicare statutes, and give rise to False Claims Act liability. The "advisor" fees paid by Defendants to referring providers in this case are no different from those proscribed by the OIG through its Advisory Opinions. Defendants' fees and other "compensation provides an obvious financial benefit to the referring physician, and it may be inferred that this benefit would be in exchange for referrals to the Lab." OIG Advisory Opinion No. 05-08, at p. 4.

74. Moreover, as in the scenario considered by the OIG's Advisory Opinion, the "consulting" and "advising" fees and other remuneration provided by Defendants have the effect of incentivizing physicians to order more tests, creating a "risk of overutilization and inappropriate higher costs to the Federal health care programs." *See* OIG Advisory Opinion No. 05-08, p. 4.

75. Defendants presented to Medicare, Medicaid, and other government programs claims for reimbursement of laboratory tests which were neither reasonable nor necessary but were ordered by physicians in exchange for kickbacks. In doing so, Defendants caused hundreds of thousands of submissions of reimbursement claims for laboratory tests that were not medically necessary. As such, each of these claims constitutes a false claim in violation of the False Claims Act (31 U.S.C. §§ 3729 *et seq*.). Defendants certified, both explicitly and implicitly, that each claim they submitted to Medicare would fully comply with all statutes and regulations, and that as Medicare providers they would comply with all pertinent statutes and regulations.

D. Defendants contract with non-employee sales persons to direct referrals in exchange for illegal remuneration.

76. Defendants enter into illegal non-employee sales agreements to induce ordering of tests from TRUE HEALTH in exchange for a commission based on a percentage of the laboratory's revenues.

77. Anti-kickback statutes prohibit entities and individuals from receiving remuneration in return for "arranging for" or "recommending" the purchase or order of an "good" or "service" reimbursed by federal health programs. 42 U.S.C. § 1320a-7b(b)(1)(B). The anti-kickback statutes likewise prohibit TRUE HEALTH from paying such remuneration. Id. Claims that induce the ordering of items or services from a violation of the anti-kickback statutes are false or fraudulent under the federal False Claims Act. 42 U.S.C. § 1320a-7b(g).

78. The OIG's guidance on the issue of contracted and commission based laboratory sales forces is instructive. Specifically, the OIG has published safe harbor regulations that precisely define arrangements and conditions which are not subject to anti-kickback violations because they would be unlikely to result in fraud or abuse. *See* HHS-OIG Advisory Opinion NO. 05-08, Issued August 2005, available at http://oig.hhs.gov/fraud/docs/advisoryopinions/2005/ao05_08.pdf; *see also* HHS-OIG Advisory Opinion NO. 99-3; *see also* HHS-OIG Advisory Opinion No. 98-10; see also HHS-OIG Advisory Opinion No. 10-23. Defendants' sales agreements do not meet these standards.

79. In the context of independent contractors, arrangements must meet seven standards, including setting forth in advance aggregate compensation based on fair market value and not determined in a manner that takes into account the volume or value of any referral or business otherwise generated between the parties. 42 C.F.R. § 1001.952(d). Defendants' arrangements cannot qualify for this safe harbor because aggregate compensation is not set out in advance, the compensation paid exceeded fair market value, and the amount of compensation is directly tied to referrals between Defendants and other parties.

80. *Bona fide* employees are also covered by safe harbor provisions. 42 U.S.C. § 1320a-7b(b)(3)(B); 42 C.F.R. § 1001.952(i). This safe harbor was specifically not extended to independent contractors because of the "existence of widespread abusive practices by salespersons who are independent contractors and, therefore, who are not under appropriate supervision and control." Medicare and State Health Care Programs; Fraud and Abuse; OIG Anti-Kickback Provisions, 56 Fed. Reg. 35952, 35981 (July 29, 1991). Again, Defendants are not protected by this safe harbor because there is no employer-employee relationship.

81. TRUE HEALTH pays contractors, such as Defendants KEVIN CARRIER, CHARLES MAIMONE and BOOMER CORNWELL, a commission based on a percentage of the laboratory's revenue in exchange for the contractor arranging for and recommending physicians who order tests that are reimbursed by federal programs. Defendants negotiated and entered into these agreements, knowing they violated anti-kickback statutes and, therefore, submitted false claims.

E. Defendants pay physicians' phlebotomists $15 per blood draw to induce physicians to order CVD panels.

82. TRUE HEALTH, to induce physicians to order CVD panels, pays physicians' phlebotomists $15 for drawing blood from patients for tests submitted to TRUE HEALTH. In certain instances, TRUE HEALTH contracts directly with the phlebotomists, paying them as "independent contractors" for each blood draw they perform for tests submitted to TRUE HEALTH. Additionally, TRUE HEALTH encourages the physicians to reduce the phlebotomists' salaries by directing the phlebotomists to "clock-out" when they draw blood for TRUE HEALTH tests submissions.

83. Furthermore, in an attempt to conceal this illegal kickback scheme TRUE HEALTH often utilizes a third-party company to enter into sham phlebotomy contracts with physicians to pay the physicians' phlebotomists the same $15 per blood draw. TRUE HEALTH sales representatives contact physicians with offers to make the physicians' phlebotomists "independent contractors" for the third-party company. Specifically, the phlebotomists are told that they can work as "independent contractors" of the third-party and receive compensation for every blood draw they perform for tests they submit to TRUE HEALTH. This is a sham designed to provide remuneration to physicians and their staff in exchange for CVD test panel orders to TRUE HEALTH.

84. TRUE HEALTH pays the third-party company a $25 draw and collection fee, per patient. From this payment, the third-party keeps approximately $10, and forwards the remaining $15 to its "independent contractors." This arrangement allows the physicians to reduce the salary they pay to the phlebotomists by having the phlebotomist "clock-out" when they draw blood for TRUE HEALTH. TRUE HEALTH encourages the physicians to have the phlebotomists "clock-out." TRUE HEALTH's arrangement with physicians and the third-party company is a deliberate violation of anti-kickback statutes.

85. Standard industry practice allows for the laboratory to pay physicians and medical assistants a nominal fee for the small amount of time it takes to draw, collect and package the specimen. Medicare, for example, provides a $3 payment to physicians for drawing a specimen. Furthermore, Medicare reimburses physicians for drawing and processing patients' blood as part of the office visit fee. Any further payment by TRUE HEALTH amounts to double payment to the physician.

86. According to the Department of Health and Human Services, Office of Inspector General (OIG), when a laboratory pays a referring physician for performing blood draws, and where the amount exceeds $3, "an inference arises that the compensation is paid as an inducement to the physician to refer patients to the laboratory." OIG Advisory Opinion No. 05-08, page 4.

87. Here, TRUE HEALTH pays the third-party a $25 draw fee per patient, and the third-party forwards $15 of that fee to the phlebotomists. This remuneration is illegal as it induces physicians to order TRUE HEALTH CVD test panels. TRUE HEALTH's direct payments to physicians' phlebotomists are also illegal as they too induce physicians to order TRUE HEALTH CVD test panels.

VII. DEFENDANTS VIOLATED THE FALSE CLAIMS ACT BY INDUCING HOSPITALS TO ORDER AND BILL FOR TESTS FRAUDULENTLY PRESENTED FOR REPAYMENT UNDER THE HOSPITALS' UNIQUE PROVIDER INFORMATION.

88. Defendants violated the False Claims Act by knowingly causing hospitals to submit fraudulent claims for payment for laboratory testing services to Medicare and other health insurance payers.

89. Defendants have engaged in a new, equally fraudulent "pass-through" billing scheme. TRUE HEALTH routes its testing through small hospitals to generate inflated payments, often seventy percent (70%) more profit for the exact same tests because of different reimbursement rates between hospitals and commercial laboratories, and the difference between in-network and out-of-network rates. This new scheme, commonly referred to as a "Hospital Outpatient Department," or "HOPD," is fraudulent on two levels: (1) the hospitals submit falsified claims for reimbursement

under their NPI number for laboratory testing not performed at the hospital in exchange for (2) a portion of the reimbursement amount, which is an illegal kickback. This scheme is gaming the system at its worst.

90. Relator's information regarding this scheme was disclosed to the Government prior to amending this complaint.

91. Medicare Part A covers payments for hospital-based treatments and care for patients covered by federally-funded medical insurance. 42 U.S.C. § 1395d. Medicare Part B covers payments for medically necessary diagnostic and treatment services for outpatient treatment from a Medicare-participating hospital. 42 U.S.C § 1395k.

92. To receive reimbursement from Medicare, a hospitals' claims for repayment are submitted under the hospitals' unique CLIA and NPI numbers.

93. A CLIA number is a representation that the particular laboratory has been certified under the Clinical Laboratory Improvement Amendments of 1988, 42 U.S.C. § 263(a). The certification issued to a hospital is for laboratory work performed in the hospital's laboratory. Medicare and Medicaid require CLIA certification as a condition of payment. 42 C.F.R. § 493.1.

94. A NPI number is a unique 10-digit identification number issued to covered health care providers by the CMS.

A. Defendants contracted with small hospitals to fraudulently benefit from higher reimbursement rates.

95. TRUE HEALTH developed its Hospital Outpatient Department ("HOPD") scheme to fraudulently induce hospitals to order additional, unnecessary tests in order to receive the higher reimbursement rates given to hospitals.

96. TRUE HEALTH contracts with small hospitals to help the hospital manage its labs. In reality, the hospital serves to "white-label" tests TRUE HEALTH performs in its own labs. In exchange, the hospital submits the billing reimbursement for the "white label" tests to Medicare and Medicaid, without having done the testing itself. TRUE HEALTH and the hospital then split the Medicare/Medicaid reimbursement fee.

97. Upon information and belief, small hospitals enter into Laboratory Reference Agreements with TRUE HEALTH and/or TRUE HEALTH OUTREACH, an entity within True Health's "family of companies" responsible for laboratory management. See, "True Health Outreach," https://truehealthdiag.com/lab-management-solutions/ (last accessed January 29, 2018); *see also* Exhibit 9 at pp. 25, 30 and 35. Through these contracts, the hospitals allow TRUE HEALTH to submit claims to Medicare and other insurance carriers for payment using the hospitals' name, CLIA and NPI numbers even though the laboratory services were not performed at or by the hospitals. To disguise this, the hospitals "white-label" the test reimbursement request, falsely labeling the test with their provider information – and implicitly certifying that it had performed the test – before submitting the claim to Medicare for reimbursement.

98. In its "Management Presentation" PowerPoint slides prepared and presented by TRUE HEALTH executives, including CEO CHRIS GROTTENTHALER, TRUE HEALTH lays out its fraudulent HOPD scheme. Under its "Accelerated Growth Model," TRUE HEALTH explains, "True Health enters into partnerships with select hospitals to provide fee-for-service disease management solutions[.] True Health becomes an extension of the hospital[.] True Health's tests are white labeled and marketed as the hospital's tests[.]" Exhibit 9 at p. 22. The presentation further notes four prospective hospitals in Texas, Kansas, Indiana, and California with between thirty-five and fifty-seven beds targeted to further its fraudulent HOPD scheme. Exhibit 9 at p. 31 ("Near-Term Prospects and Targeting").

99. TRUE HEALTH uses a "general acute care/critical access" hospital case study in its presentation to demonstrate the economic advantages of its fraudulent HOPD scheme. Exhibit 9 at p. 30. In the example, TRUE HEALTH shows a hospital with a projected annual revenue of $12.6 million, of which half ($6.3 million) is paid to TRUE HEALTH while the hospital, despite absorbing expenses, makes $4.1 million – a staggering sixty-five percent profit margin. Exhibit 9 at p. 30.

100. TRUE HEALTH's presentation goes on to further demonstrate the rapid success and economic growth of this fraudulent "hospital partnership" scheme. In only nine months, TRUE HEALTH's hospital "Payer Mix" increased from 4.7 percent to 40.6 percent – an eye-popping eight hundred sixty four percent increase. Exhibit 9 at p. 25. This impossible growth rate is indicative of

yet another dubious scheme concocted by TURE HEALTH in order to not draw government attention to its fraudulent practices.

B. Defendants induced doctors to order tests so it could use the hospitals' provider information to receive higher reimbursements.

101. Through its other fraudulent sales schemes, *see* Sec. VII *supra* (waiver of co-payments/deductibles, inflated consulting fees, sham Advisory Board, volume-based commission sales agreements and draw fee phlebotomist agreements), TRUE HEALTH pays and induces physicians to send patient specimens to the hospitals' laboratories.

102. On information and belief, the patients reportedly being tested by the hospitals' laboratories are often times not even from hospital-accredited physicians, but, rather, are patients from other referring physicians whose offices are hundreds of miles away from the hospital. For example, on information and belief, one doctor in Texas referring specimens through TRUE HEALTH's HOPD scheme is over 200 miles away from the hospital.

103. TRUE HEALTH and the hospitals conspire to add affiliate physicians to the hospitals' network so that these physicians' orders can be billed at the inflated in-network hospital rates. On information and belief, those doctors receive kickbacks for creating these sham affiliations, in the form of a percentage of the reimbursement received for each test ordered. As such, each of these claims constitutes a false claim in violation of the False Claims Act (31 U.S.C. §§ 3729 *et seq*.). Defendants certified, both explicitly and implicitly, that each claim they submitted to Medicare would fully comply with all statutes and regulations, and that as Medicare providers they would comply with all pertinent statutes and regulations.

C. Defendants knowingly caused fraudulent "White Labeled" claims to be submitted to Medicare, Medicaid and other insurance carriers for reimbursement.

104. Under TRUE HEALTH's fraudulent HOPD scheme, the hospitals' laboratories send the patient specimens to TRUE HEALTH's laboratory for testing. After performing the tests, TRUE HEALTH then sends these laboratory results back to the hospitals for "white labeling" and submission to Medicare and other insurance companies for reimbursement.

105. For example, Exhibit 10 is a test requisition report for Faith Community Hospital in Jacksboro, Texas, a small hospital with only forty-one beds. On Exhibit 10 at p. 3, the report notes, "All tests were analyzed by True Health Diagnostics LLC, 737 N. 5th Street, Suite 103, Richmond VA . . . unless otherwise noted." Further, on p. 4 of Exhibit 10, the report notes, "Tests noted with a "[9]" were analyzed at Faith Community Hospital." Yet, only one test of the twenty-one with reported results is noted with a "[9]": "Glucose (mg/dL)." Exhibit 10 at p. 2.

106. The "white labeled" claims are submissions for reimbursement for laboratory services not performed by the hospitals, laboratory services ordered to be performed by TRUE HEALTH, not by the hospitals. On information and belief, laboratory services were submitted to TRUE HEALTH by referring physicians, some of whom are located hundreds of miles away from the hospitals. The laboratory results were then submitted to the providers who ordered the tests on forms with the hospitals' logos and the hospitals' CLIA and NPI numbers and address. Exhibit 10 at p. 1.

107. Yet, the claims submitted by the hospital were not for laboratory work performed in the hospitals' laboratories, despite certifying to the contrary when it submitted the claims under its CLIA number. Each of the hospitals' "white label" tests is a knowing misrepresentation and false certification that it had tested the specimens. As such, each of these claims constitutes a false claim in violation of the False Claims Act (31 U.S.C. §§ 3729 *et seq*.). Defendants certified, both explicitly and implicitly, that each claim they submitted to Medicare would fully comply with all statutes and regulations, and that as Medicare providers they would comply with all pertinent statutes and regulations.

D. Defendants knowingly caused fraudulent "White Labeled" claims to be submitted to private insurance carriers for reimbursement.

108. Unlike Medicare and Medicaid, managed care companies contract with providers and negotiate fixed reimbursement rates. These are known as "fee-for-service" contracts and are only available to the contracted "in-network" providers. TRUE HEALTH circumvents these contracts by inducing in-network providers to "white label" its tests and thereby receive the contractual benefits of higher reimbursement rates.

109. Managed care companies, such as Blues Cross/Blue Shield of California, United Healthcare, Aetna, and Cigna administer a variety of health and welfare benefit plans. As part of their fiduciary responsibilities to those plans, the managed care companies are responsible for controlling healthcare costs.

110. One way managed care companies control costs is by entering into networks of healthcare providers whereby the providers agree to accept fixed rates for services in exchange for access to plan members. The managed care companies' arrangements with providers benefit the plans and their members by controlling overall health care costs and increasing the quality of medical care.

111. Hospitals are typically contracted with various managed care companies to become "in-network." Generally, hospital fee-for-service reimbursement rates are higher – sometimes, far higher – than commercial laboratory reimbursement rates that laboratories like TRUE HEALTH would normally receive.

112. In contrast, TRUE HEALTH is "out-of-network" with most managed care plans. Exhibit 9 at p. 25. By contracting with these small "in-network" hospitals through its HOPD scheme, TRUE HEALTH is able to take advantage of the hospitals' higher reimbursement rates.

113. The economics underlying this blatant fraud are staggering. "Under its hospital partnership strategy, True Health estimates the average economics will increase from $300-315 to approximately $500 as it moves in-network." Exhibit 9 at p. 25. This amounts to a 67% to 59% increase attributable to TRUE HEALTH's HOPD scheme.

114. As a result of TRUE HEALTH's HOPD scheme to route its testing through these small "in-network" hospitals, TRUE HEALTH is able to generate higher profits for the exact same tests. As such, each of these claims constitutes a false claim in violation of the California Insurance Fraud Prevention Act, California Insurance Code § 1871.7(a).

E. Defendants' agreement to split the reimbursement is an illegal kickback.

115. Again, the anti-kickback statutes prohibit entities and individuals from receiving remuneration in return for "arranging for" or "recommending" the purchase or order of an "good" or "service" reimbursed by federal health programs. 42 U.S.C. § 1320a-7b(b)(1)(B). The anti-

kickback statutes likewise prohibit TRUE HEALTH from paying such remuneration. Id. Claims that induce the ordering of items or services from a violation of the anti-kickback statutes are false or fraudulent under the federal False Claims Act. 42 U.S.C. § 1320a-7b(g). Defendants' "white label" HOPD scheme is a blatant kick-back scheme.

116. Despite laboratory specimens being sent to and tested by TRUE HEALTH, the hospitals misrepresent to Medicare and insurance carriers that the specimens were tested by and at the hospitals, causing the insurers to pay higher reimbursement rates than they would have otherwise paid to TRUE HEALTH.

117. For its part, the hospitals are "reimbursed" by TRUE HEALTH, which bills under the hospitals' name, CLIA and NPI numbers. TRUE HEALTH splits the Medicare and insurance reimbursement amount with the hospitals. This is a blatant kick-back: for having only supplied its CLIA and NPI number and submitting the claims for funneling specimens to TRUE HEALTH, the hospitals receive a portion of the reimbursement. As such, each of these claims constitutes a false claim in violation of the False Claims Act (31 U.S.C. §§ 3729 *et seq*.).

VIII. DEFENDANTS VIOLATED THE FEDERAL FALSE CLAIMS ACT BY BILLING FOR MEDICALLY UNNECESSARY LABORATORY TESTS.

118. Defendants violated the False Claims Act by submitting claims for payment for laboratory testing services that Defendants knew were not medically necessary. Section 1862 of the Social Security Act provides, in pertinent part: "Notwithstanding any other provision of this title, no payment may be made under [Medicare] for any expenses incurred for items or services . . . which . . . are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." 42 U.S.C. 1395y(a)(1)(A).

119. Defendants violated 42 U.S.C. 1395y(a)(1)(A) by ordering medically unnecessary laboratory tests. Defendants' practice of pre-selecting tests and discouraging doctors from de-selecting a test violates established Medicare regulations as all diagnostic tests "must be ordered by the physician who furnishes a consultation or treats a beneficiary for a specific medical problem . . .", 42 C.F.R. § 410.32(a), and "tests not ordered by the physician who is treating the beneficiary are not reasonable and necessary." *Id*.

120. Medicare and other federal health care programs require as a condition of coverage that services rendered must be reasonable and medically necessary. 42 U.S.C. § 1395y(a)(1)(A). Defendants presented to Medicare claims for reimbursement of laboratory tests which were neither reasonable nor necessary. As such, each of these claims constitutes a false claim in violation of the False Claims Act (31 U.S.C. § 3729 et seq.). Defendants certified, both explicitly and implicitly, that each claim they submitted to Medicare would fully comply with all statutes and regulations, and that as Medicare providers they would comply with all pertinent statutes and regulations.

A. Defendants require the ordering of extensive panels of duplicative and medically unnecessary tests.

121. Defendants induced doctors to order panels comprised of tests that were not medically reasonable or necessary. Test requisition forms encourage physicians to order bundles, or "panels," of pre-selected tests, not all of which are necessary for each patient and were redundant tests. Specifically, physicians were encouraged to order only a "Baseline Panel" comprised of eighty-five different tests or a "Follow Up" Panel comprised of eighty-five tests. (See Exhibit 6). Defendants instructed physicians to simply circle the "B/L" or "F/U" box over the panel they wanted, regardless of the medical utility of the tests. By running each of these panels, Defendants were running duplicative and medically unnecessary tests.

122. As just one of many examples of unnecessary, duplicative tests, in TRUE HEALTH's "Baseline Panel," two of the eighty-five tests are the Apo-B and LDL-P tests. These same two tests are also part of the "Follow-Up" Panel. Both of these tests measure total LDL particles. There is no medical benefit to including both of these tests because they provide the same medical information and treatment would not be affected by including both tests. Both tests are pre-selected by Defendants as part of their panels; doctors do not have the option to de-select one of the tests. Defendants then perform, and bill Medicare for, each of the tests. Defendants charge Medicare in excess of $19.95 for the Apo-B test, and $42.93 for the LDL-P test. Each time they do so, Defendants violate the False Claims Act.

123. Other examples of unnecessary, duplicative tests included on TRUE HEALTH's routine panels are: (1) PLAVIX, a test with limited to use only for patients suffering a stroke where

the doctor is considering treatment with Plavix; (2) Galactin-3, a test only appropriate for patients suffering heart failure; (3) prothrombin, a test only medically necessary for patients with blood clots; and (4) Troponin, a test which should only be used in the emergency room for patients presenting with chest pain. None of these tests are appropriate as a screening tool for the general population.

B. Defendants fraudulently bill under the Texas Medicare Administrative Contractor's ("MAC") Fee Schedule for CVD tests actually performed at their Virginia lab.

124. In violation of clearly established Medicare rules, Defendants bill Medicare for CVD tests performed at their Richmond, Virginia lab as though the tests were performed at their Texas lab. Defendants do this in order to bill under the Texas Medicare Administrative Contractor's ("MAC") fee schedule rather than the Virginia MAC's fee schedule because the CVD tests performed in Virginia, are not reimbursable under the Virginia MAC fee schedule. Defendants' billing scheme is an intentional and blatant violation of Medicare rules, which require lab tests to be billed under the MAC fee schedule for the state in which the tests were actually performed:

> Jurisdiction of payment requests for laboratory services furnished by an independent laboratory except where indicated in §50.5.1 and §50.5.2, lies with the A/B MAC (B) serving the area in which the laboratory test is performed. Jurisdiction is not affected by whether or not the independent laboratory uses a central billing office and whether or not the laboratory provides services to customers outside its A/B MAC (B)'s service area. **The location where the independent laboratory performed the test determines the 50.appropriate billing jurisdiction** [sic.]. Therefore, even if the sample originates in a different jurisdiction from where the sample is being tested, the claim would still be filed in the jurisdiction where the test was performed.

Center for Medicare Services, Sec. 50.5 – Jurisdiction of Claims, "Chapter 16 – Laboratory Services," *Medicare Claims Processing Manual*, at p. 37, *available at* https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c16.pdf (emphasis added).

125. Defendants' scheme is designed to ensure they continue to profit from their lucrative CVD panels, which contain expensive, specialized tests that Defendants could/can only perform at their Virginia lab where they have the necessary equipment to do so.

126. When Defendants first implemented their CVD test-shipping scheme, they sent blood samples received at their Virginia lab to their Texas lab to be accessioned in Texas, and then shipped the very same blood samples back to their Virginia lab for testing. Defendants' scheme, however, has evolved over time and become even more robust, streamlined, and blatantly illegal. Currently, in order to streamline the process, Defendants send only a portion of a given blood sample from Virginia to Texas to be accessioned while maintaining enough of the blood sample in Virginia to perform CVD testing. From the scheme's inception, however, Defendants have billed Medicare as though the tests were performed in Texas, even though their Texas lab did or does lack the necessary equipment to perform many of the specialized CVD tests included in their CVD panels.

127. This meandering process allows Defendants to avoid a recently enacted regional Medicare policy that bans CVD test panels because the policy only applies to tests performed in the states of Virginia, West Virginia, South Carolina, and North Carolina. Aware that this new Medicare policy banned reimbursement for CVD panels performed in Virginia, Defendants intentionally designed and implemented this scheme specifically to circumvent the new Medicare Policy.

128. This new policy is what is referred to as a Local Coverage Determination ("LCD") and is officially titled "MoIDX: Biomarkers in Cardiovascular Risk Assessment," or "L36129." L36129 is administered by Palmetto GBA, the local MAC for Virginia, West Virginia, South Carolina, and North Carolina. L36129 came into effect on October 5, 2015. L36129 provides that cardio vascular risk assessment panels performed on patients with pre-existing risk factors for cardio vascular diseases are not medically reasonable or necessary and, therefore, not covered by Medicare. These are the precise types of CVD panels Defendants perform and seek reimbursement for from Medicare. Specifically, L36129 (attached hereto as Exhibit 7) states, *inter alia*, the following:

> CV risk assessment panels, consisting of various combinations of biochemical, immunologic, hematologic, and molecular tests, is considered screening when performed on an asymptomatic patient, and, as such, are not a Medicare benefit. **These CV risk assessment panels are not medically reasonable and necessary if performed on a patient with existing risk factors including but not limited to pre-diabetes or diabetes, smoking, hypertension or hyperlipidemia because these panels are not specific to a patient's lipid abnormality or disease**.

Palmetto Local Coverage Determination: MoIDX: Biomarkers in Cardiovascular Risk Assessment (L36129) (Exhibit 7)

129. Medicare requires that MACs, like Virginia's Palmetto GBA, pay for tests on the basis of the fee schedule in effect in the jurisdiction where the test was performed. (*See* CMS Medicare Claims Processing Manual, Chapter 16-Laboratory Services, section 50.1-Referring Laboratories ("Every carrier shall base payment for a referred service on the fee schedule for the jurisdiction in which the service was performed, i.e., where the test was performed).) The fee schedule is subject to the LCDs effective in its jurisdiction. Thus, each CVD panel containing CVD tests that Defendants perform in Virginia is subject to L36129, which is the policy in effect in Virginia, the jurisdiction in which the tests are performed.

130. Instead of complying with this straightforward Medicare rule, Defendants deliberately conceal from the MAC they actually bill, the Texas MAC, that the most expensive and specialized CVD tests contained in their CVD panels are actually performed in Virginia. Defendants do so in order to circumvent L36129, which bans reimbursement for the type of CVD panels that Defendants perform. Believing the tests were accessioned and performed in Texas, the Texas MAC applies its local fee schedule, which is not subject to or otherwise affected by L36129 or any similar rule. Accordingly, Defendants obtain reimbursement from Medicare for their highly profitable CVD panels, in direct contravention of clearly established Medicare rules. Defendants' scheme also allows and/or allowed Defendants to obtain reimbursement for tests performed in Virginia during a period in which Defendants were not licensed to submit claims to Palmetto GBA, the local MAC for Virginia.

IX. DEFENDANTS VIOLATED MULTIPLE STATE FALSE CLAIMS ACTS BY CHARGING MEDICAID PROGRAMS IN EXCESS OF THEIR LOWEST CHARGE AND PROVIDING PHYSICIANS WITH ILLEGAL KICK-BACKS.

131. Title XIX of the Social Security Act and Title 42 of the Code of Federal Regulations authorize individual states to develop and manage their own Medicaid programs. Medicaid is a joint federal-state program that provides health care benefits, including laboratory services coverage, for certain groups including the poor and disabled. The funding for Medicaid is shared between the federal and state governments. Each state is required to implement a state plan containing certain

specified minimum criteria for coverage and payment of claims in order to qualify for federal funds for Medicaid expenditures. 42 U.S.C. § 1396a. The federal Medicaid statute sets forth the minimum requirements for state Medicaid programs to qualify for federal funding. Id. The federal portion of each state's Medicaid payments, known as the Federal Medicaid Assistance Percentage is based on a state's per capita income compared to the national average. 42 U.S.C. § 1396d (b).

132. In addition to the Medicaid statutes, many states also have their own false claims statutes, which mirror the federal FCA. Defendants' schemes violated these state statutes. These violations are even more egregious because they have been accomplished through knowing violations of the long-established federal anti-kickback laws.

A. Defendants violated Georgia's lowest charge requirement.

133. The Georgia Department of Community Health, Division of Medical Assistance ("Division") is solely responsible for the administration, including reimbursement to providers, of Georgia's Medicaid program. According to the Division's guidance, providers are required to bill the Division "their usual and customary fees," which was defined as "the lowest rate charged to private patients, other third party payers and insurance carriers, health maintenance organizations or other members of the general public for comparable services . . . includ[ing] any special price or discounts offered to such patients." Schedule of Maximum Allowable Payments for Clinical Laboratory and Anatomical Pathology Services (given force of law by OCGA § 49-4-142).

134. The lowest rate limitation is also found in the Georgia Medicaid fee schedule "preamble" and in both the Georgia Medicaid Provider Manual ('Provider Manual'), and a similar manual specifically directed at laboratories (the Policies And Procedures For Independent Lab Services Program, or the 'Laboratory Provider Manual'). Indeed, the Georgia Medicaid fee schedule states:

> As required by Divisional policy, providers must bill the Division their usual and customary fees. "Usual and customary" means the lowest rate charged to private patients, other third party payers and insurance carriers, health maintenance organizations or other members of the general public for comparable services. The lowest rate includes any special price or discounts offered to such patients. Providers must not change their fees to the upper limits in this schedule, even if these fees are higher than the maximum allowable payments for the services rendered.

Schedule of Maximum Allowable Payments for Clinical Laboratory and Anatomical Pathology Services (emphasis added).

135. Both the Georgia Medicaid fee schedule and the Medicaid manual make expressly clear that the lowest charge rule is a condition of payment. Even more clearly, the Medicaid Provider Manual states, on its very first page: "This manual contains basic information concerning Georgia's Medicaid/PeachCare for Kids program and is intended for use by all participating providers. Along with the Statement of Participation, this manual encompasses the terms and conditions for receipt of reimbursement." *See* Exhibit 8 (Provider Manual), at 1 (emphasis added).

136. Simply put, TRUE HEALTH was required to bill Georgia Medicaid at its lowest price. Charges in excess of the maximum allowable fees are subject to recovery under both OCGA § 49-4-146.1, and the Georgia False Medicaid Claims Act, OGCA § 49-4-168 et seq.

137. Defendant TRUE HEALTH readily accepts payments from private insurance provider United Healthcare, Aetna, and Cigna to provide them with lab tests at a rate, on average 62% lower than the Georgia Medicaid reimbursement rate. (Exhibit 3). Under Georgia's Medicaid program, TRUE HEALTH is required to provide this same discount to Georgia's Medicaid program. Consequently, every test that TRUE HEALTH has billed Georgia's Medicaid program at a rate above their lowest rate to other payors constitutes a false claim.

138. Defendants' fraudulent schemes as detailed above have also defrauded Georgia's Medicaid program. Defendants submitted electronic invoices for clinical laboratory tests directly to the Division for Medicaid reimbursement, knowing both that the tests were induced by providing illegal kickbacks and the charges were in excess of the Medicaid reimbursement rate for each test performed. In submitting those claims for payment to the Division, Defendants represented that their fees complied with state Medicaid regulations. Those representations were false and violated the Georgia Medicaid statute, 49-4-146.1 and the Georgia False Medicaid Claims Act, OGCA § 49-4-168 et seq.

139. The chart included below provides examples of Defendants' overcharges to the Georgia Medicaid program and shows that Georgia Medicaid was billed and paid 62% more on average than other payors.

Test Name	CPT	GA Medicaid	United Health	Aetna	Cigna	Lowest Charge	% Over-charge
Lipid Panel	80061	$16.85	$8.42	$16.02	$12.56	$8.42	50%
Lp-PLAC2	83698	$42.69	$0.00	$0.00	$26.04	$0.00	100%
HS-CRP	86141	$16.28	$7.33	$15.49	$9.97	$7.33	55%
sd-LDL	83701	$31.21	$14.05	$0.00	$0.00	$0.00	100%
Lipoprotien (a)	83695	$16.28	$21.60	$41.10	$9.97	$9.97	39%
Apo A1	82172	$19.49	$0.00	$16.86	$11.82	$0.00	100%
Apo B	82172	$19.49	$0.00	$16.86	$11.82	$0.00	100%
Homocysteine	83090	$21.21	$10.61	$0.00	$12.93	$0.00	100%
Vitamin D	82306	$37.22	$18.61	$35.41	$22.71	$18.61	50%
Adiponectin	83516	$13.45	$7.25	$9.24	$8.86	$7.25	46%
C-Peptide	84681	$19.98	$13.08	$25.48	$16.06	$13.08	35%
Apo E	81401	$112.00	$69.55	$65.00	$0.00	$0.00	100%
Factor V Leiden	81241	$40.00	$54.68	$0.00	$0.00	$0.00	100%
Factor II	85201		$58.71	$50.58	$0.00		
MTHFR	81291	$40.00	$136.00	$0.00	$0.00	$0.00	100%
TSH	84443	$21.12	$10.56	$20.09	$12.93	$10.56	50%
Insulin	83525	$14.38	$7.19	$13.68	$8.86	$7.19	50%
Hemoglobin A1C	83036	$12.20	$6.10	$11.61	$7.39	$6.10	50%
Vitamin B-12	82607	$18.95	$9.48	$18.50	$11.63	$9.48	50%
Intact PTH	83970	$51.90	$25.45	$41.07	$31.76	$25.45	51%
T4, Free	84439	$11.34	$5.67	$8.97	$7.02	$5.67	50%
T4, Total	84436	$8.65	$4.32	$6.84	$5.35	$4.32	50%
T3, F	84481	$21.30	$10.65	$15.94	$13.11	$10.65	50%
T3, Total	84480	$16.03	$8.91	$14.11	$10.89	$8.91	44%
Testosterone, Total	84403	$32.47	$16.24	$25.69	$19.76	$16.24	50%
Testosterone, F	84402	$32.01	$16.01	$25.34	$19.57	$16.01	50%
Estradiol	82670	$35.14	$17.57	$27.81	$21.42	$17.57	50%
IGF-1	84305	$26.73	$13.37	$19.73	$16.25	$13.37	50%
Progesterone	84144	$25.61	$13.12	$20.75	$16.06	$13.12	49%
FSH	83001	$23.37	$11.69	$18.50	$14.22	$11.69	50%
LH	83002	$23.29	$11.65	$18.43	$14.22	$11.65	50%

/ / /

/ / /

/ / /

B. Defendants violated Massachusetts's lowest charge requirement and anti-kickback rules.

140. Massachusetts's Medicaid program, known as "MassHealth," is administered in part by the Commonwealth's Department of Health Care Finance and Policy ("DHCFP"). MassHealth's reimbursement procedures are governed, in part, by Massachusetts's Public Welfare statutes. Specifically, General Laws chapter 118E, section 41 prohibits providers from offering "any bribe or rebate, directly or indirectly, overtly or covertly, in cash or in kind to induce" the purchase of services for which MassHealth pays.

141. The Code of Massachusetts Regulations also requires providers to bill MassHealth lowest of either the provider's "usual and customary charge," the allowable fees listed in 114.3 CMR 20.05, or the rate recognized under 42 U.S.C. §§ 1395 1(h) for such tests. 1143. Code Mass. Regs. § 20.04(1). The Regulations define "usual and customary charge" as "[t]he lowest fee charged by an independent clinical laboratory for any laboratory service." 1143. Code Mass. Regs. § 20.05.

142. Charges in excess of the maximum allowable fees are subject to recovery under both the Medicaid provider statute, General Laws chapter 118E, § 38, and the Massachusetts False Claim Act, G.L. c. 12, §§ 5A-5O.

143. Defendant TRUE HEALTH readily accepts payments from private insurance provider United Healthcare, Aetna, and Cigna to provide them with lab tests, on average at a rate 51% lower than the Medicare reimbursement rate (Exhibit 4). Under Massachusetts' Medicaid program, TRUE HEALTH is required to provide this same discount to Massachusetts' Medicaid program. Consequently, every test that TRUE HEALTH has billed Massachusetts' Medicaid program at a rate above their lowest rate to other payors constitutes a false claim.

144. Defendants' fraudulent schemes as detailed above have also defrauded the MassHealth program. Defendants submitted electronic invoices for clinical laboratory tests directly to DHCFP for MassHealth reimbursement, knowing both that the tests were induced by providing illegal kickbacks and the charges were in excess of the MassHealth reimbursement rate for each test performed. In submitting those claims for payment to MassHealth, Defendants represented that their fees complied with state MassHealth regulations. Those representations were false and violated the

Medicaid provider statute, General Laws chapter 118E, § 38, and the Massachusetts False Claim Act, G.L. c. 12, §§ 5A-5O.

145. The chart included below provides examples of Defendants' overcharges to the Massachusetts Medicaid program and shows that Massachusetts Medicaid was billed and paid 51% more on average than other payors.

Test Name	CPT	MA Medicaid	United Health	Aetna	Cigna	Lowest Charge	% Over-charge
Lipid Panel	80061	$14.33	$8.42	$16.02	$12.56	$8.42	41%
Lp-PLAC2	83698	$36.32	$0.00	$0.00	$26.04	$0.00	100%
HS-CRP	86141	$13.85	$7.33	$15.49	$9.97	$7.33	47%
sd-LDL	83701	$26.56	$14.05	$0.00	$0.00	$0.00	100%
Lipoprotien (a)	83695	$13.85	$21.60	$41.10	$9.97	$9.97	28%
Apo A1	82172	$16.58	$0.00	$16.86	$11.82	$0.00	100%
Apo B	82172	$16.58	$0.00	$16.86	$11.82	$0.00	100%
Homocysteine	83090	$18.05	$10.61	$0.00	$12.93	$0.00	100%
Vitamin D	82306	$31.68	$18.61	$35.41	$22.71	$18.61	41%
Adiponectin	83516	$12.26	$7.25	$9.24	$8.86	$7.25	41%
C-Peptide	84681	$22.26	$13.08	$25.48	$16.06	$13.08	41%
Apo E	81401		$69.55	$65.00	$0.00	$0.00	
Factor V Leiden	81241		$54.68	$0.00	$0.00	$0.00	
MTHFR	81291		$136.00	$0.00	$0.00	$0.00	
TSH	84443	$17.98	$10.56	$20.09	$12.93	$10.56	41%
Insulin	83525	$12.23	$7.19	$13.68	$8.86	$7.19	41%
Hemoglobin A1C	83036	$10.39	$6.10	$11.61	$7.39	$6.10	41%
Vitamin B-12	82607	$16.01	$9.48	$18.50	$11.63	$9.48	41%
Intact PTH	83970	$44.16	$25.45	$41.07	$31.76	$25.45	42%
T4, Free	84439	$9.65	$5.67	$8.97	$7.02	$5.67	41%
T4, Total	84436	$7.35	$4.32	$6.84	$5.35	$4.32	41%
T3, F	84481	$18.13	$10.65	$15.94	$13.11	$10.65	41%
T3, Total	84480	$15.17	$8.91	$14.11	$10.89	$8.91	41%
Testosterone, Total	84403	$27.63	$16.24	$25.69	$19.76	$16.24	41%
Testosterone, F	84402	$27.25	$16.01	$25.34	$19.57	$16.01	41%
Estradiol	82670	$29.90	$17.57	$27.81	$21.42	$17.57	41%
IGF-1	84305	$18.09	$13.37	$19.73	$16.25	$13.37	26%
Progesterone	84144	$22.33	$13.12	$20.75	$16.06	$13.12	41%
FSH	83001	$19.88	$11.69	$18.50	$14.22	$11.69	41%

Test Name	CPT	MA Medicaid	United Health	Aetna	Cigna	Lowest Charge	% Over-charge
LH	83002	$19.82	$11.65	$18.43	$14.22	$11.65	41%

C. Defendants violated the California Insurance Fraud Prevention Act by waiving patient co-pays and deductibles, and providing kickbacks.

146. Pursuant to California Insurance Code § 1871.7(a), it is "unlawful to knowingly employ runners, cappers, steerers, or other persons to procure clients or patients to perform or obtain services or benefits pursuant . . . or to procure clients or patients to perform or obtain services or benefits under a contract of insurance or that will be the basis of a claim against an insured individual or his or her insurer."

147. Like the Federal False Claims Act, any person or entity that violates § 1871.7(a) is subject to a civil penalty of up to $10,000 for each claim submitted to an insurer for payment. The person or entity is also subject to treble damages for the amount of the claim for compensation billed to the insurer.

148. Defendants' fraudulent schemes circumvent insurance companies' safeguards against unreasonable and excessive charges for routine healthcare services. Under the Medicare program, "Routine waiver of deductibles and co-payments by charge-based providers, practitioners or suppliers is unlawful because it results in . . . false claims . . . [and] excessive utilization of items and services paid for by Medicare. HHS OIG Special Fraud Alerts, available at https://oig.hhs.gov/fruad/docs/alertsandbulletins/121994.html (Dec. 19, 1994).

149. Defendants' fraudulent kickback schemes outlined above also violate California Insurance Code § 1871.7(a), and therefore subject Defendants to treble damages for the amount of the claim for compensation billed to the insurer.

150. Managed care companies, such as Blues Cross/Blue Shield of California, United Healthcare, Aetna, and Cigna administer a variety of health and welfare benefit plans. As part of their fiduciary responsibilities to those plans, the managed care companies are responsible for controlling healthcare costs.

151. One way managed care companies control costs is by entering into networks of healthcare providers whereby the providers agree to accept fixed rates for services in exchange for access to plan members. The managed care companies' arrangements with providers benefit the plans and their members by controlling overall health care costs and increasing the quality of medical care. Members who receive services from participating, or "in-network," providers benefit from the providers agreeing not to bill the patient for any difference between their plan's reimbursement to the provider and the provider's billed charge.

152. Plan members are free to use out-of-network providers, but the members must pay a portion of the cost (through co-payments, co-insurances or deductible payments) of treatment by out-of-network providers. Generally, out-of-network providers charge much higher rates than in-network providers, which incentivizes members to choose in-network providers and moderate their demand for out-of-network services. Likewise, the patient's burden in paying a portion of the costs ensures that providers are not charging rates untethered to the actual costs or market for providing medical services.

153. Defendants undermine this safeguard by fraudulently waiving patient deductibles and co-payments. Defendants lure patients from health plans administered by managed care companies by misrepresenting those patients' responsibilities under the plans, promising not to collect co-payments, and promising not to seek reimbursement for any remaining portion of the patients' bills that are uncovered by the plan.

154. Defendants further undermine this safeguard by inducing "in-network" providers to fraudulently present claims for payment under their provider information. Defendants entice in-network providers to "white label" their tests by splitting high reimbursement payments in exchange for doing little to no work.

155. By misleading plan members that they are not responsible for any deductible or co-payments and exploiting contractual relationships with providers for their own gain, TRUE HEALTH increases the volume of its business while simultaneously increasing the damage to the managed care companies and the plans they serve.

X. CAUSES OF ACTION

FIRST CAUSE OF ACTION

On Behalf of the United States

Federal False Claims Act, Presenting False Claims

31 U.S.C. § 3729(a)(1)(A)

156. Plaintiffs incorporate by reference and reallege all of the allegations contained in paragraphs 1 through 146 of this Complaint as though fully set forth herein.

157. Defendants knowingly (as defined in 31 U.S.C. § 3729(b)(1)) presented or caused to be presented false claims for payment or approval to an officer or employee of the United States.

158. Defendants knowingly presented false records and statements, including but not limited to bills, invoices, requests for reimbursement, and records of services, in order to obtain payment or approval of charges by the Medicare, Medicaid, and other government-funded programs that were higher than they were permitted to claim or charge by applicable law. Among other things, Defendants knowingly submitted false claims for Medicare, Medicaid, and other government programs' business that was obtained by means of, and as a result of, illegal kickbacks, and as a result of Defendants' illegally billing Medicare, Medicaid, and other government programs for (1) lab test that Defendants did not perform, in volumes in excess of thirty-percent of Defendants' total test volume; (2) medically unnecessary test panels including medically unnecessary tests that Defendants pre-select and medically unnecessary tests performed in Virginia but fraudulently billed for under the Texas Medicare Administrative Contractor's fee schedule; and (3) "white labeled" tests performed under Defendants' "pass-through billing" scheme.

159. Defendants knowingly made, used, and caused to be made and used false certifications that their claims, and all documents and data upon which those claims were based, were accurate, and were supplied in full compliance with all applicable statutes and regulations.

160. The conduct of Defendants violated 31 U.S.C. § 3729(a)(1)(A) and was a substantial factor in causing the United States to sustain damages in an amount according to proof.

/ / /

/ / /

SECOND CAUSE OF ACTION

On Behalf of the United States

Federal False Claims Act, Making or Using False Records or Statements Material to Payment or Approval of False Claims

31 U.S.C. § 3729(a)(1)(B)

161. Plaintiffs incorporate by reference and reallege all of the allegations contained in paragraphs 1 through 151 of this Complaint as though fully set forth herein.

162. Defendants knowingly (as defined in 31 U.S.C. § 3729(b)(1)) made, used, or caused to be made or used false records or statements material to false or fraudulent claims.

163. Defendants knowingly made, used, and/or caused to be made and used false records and statements, including but not limited to bills, invoices, requests for reimbursement, and records of services, that were material to the payment or approval of charges by the Medicare, Medicaid, and other government programs that were higher than they were permitted to claim or charge by applicable law. Among other things, Defendants knowingly submitted false claims for Medicare, Medicaid, and other government programs' business that was obtained by means of, and as a result of, illegal kickbacks, and as a result of Defendants' illegally billing Medicare, Medicaid, and other government programs for (1) lab test that Defendants did not perform, in volumes in excess of thirty-percent of Defendants' total test volume; (2) medically unnecessary test panels including medically unnecessary tests that Defendants pre-select and medically unnecessary tests performed in Virginia but fraudulently billed for under the Texas Medicare Administrative Contractor's fee schedule; and (3) "white labeled" tests performed under Defendants' "pass-through billing" scheme.

164. Defendants knowingly made, used, and caused to be made and used false certifications that their claims, and all documents and data upon which those claims were based, were accurate, and were supplied in full compliance with all applicable statutes and regulations.

165. The conduct of Defendants violated 31 U.S.C. § 3729(a)(1)(B) and was a substantial factor in causing the United States to sustain damages in an amount according to proof.

/ / /

/ / /

THIRD CAUSE OF ACTION

On Behalf of the United States

Federal False Claims Act, Conspiracy to Commit Violations

31 U.S.C. § 3729(a)(1)(C)

166. Plaintiffs incorporate by reference and reallege all of the allegations contained in paragraphs 1 through 156 of this Complaint as though fully set forth herein.

167. Defendants knowingly (as defined in 31 U.S.C. § 3729(b)(1)) conspired to commit violations of substantive portions of the False Claims Act, including but not limited to subparagraphs (A), (B), and (G) of 31 U.S.C. § 3729.

168. Defendants conspired to: (1) knowingly present false records and statements; (2) knowingly make, use, and/or cause to be made and used false records and statements; and (3) knowingly make, use, or cause to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly concealed or knowingly and improperly avoided or decreased an obligation to pay or transmit money or property to the Government.

169. The conduct of Defendants violated 31 U.S.C. § 3729(a)(1)(C) and was a substantial factor in causing the United States to sustain damages in an amount according to proof.

FOURTH CAUSE OF ACTION

In the Alternative

On Behalf of the United States

Federal False Claims Act, Retention of Proceeds to Which Not Entitled

31 U.S.C. § 3729(a)(1)(G)

170. Plaintiffs incorporate by reference and reallege all of the allegations contained in paragraphs 1 through 160 of this Complaint as though fully set forth herein.

171. In the alternative, Defendants knowingly made, used, or caused to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly concealed or knowingly and improperly avoided or decreased an obligation to pay or transmit money or property to the Government.

172. As discussed above, Defendants received far more money from the Medicare programs than they were entitled to. Defendants knew that they had received more money than they were entitled to, and avoided their obligation to return the excess money to the Government.

173. The conduct of Defendant violated 31 U.S.C. § 3729(a)(1)(G) and was a substantial factor in causing the United States to sustain damages in an amount according to proof.

FIFTH CAUSE OF ACTION

On Behalf of the State of California

California Insurance Frauds Prevention Act, Employment of Runners, Cappers and Steerers or Other Persons to Procure Patients

Cal. Ins. Code § 1871.7(a)

Against All Defendants

174. Plaintiffs incorporate by reference and reallege all of the allegations contained in paragraphs 1 through 164 of this Complaint as though fully set forth herein.

175. Pursuant to California Insurance Code §1871.7(a), it is unlawful to knowingly employ runners, cappers, steerers, or other persons to procure patients for the purpose of submitting a claim to that patient's insurance carrier.

176. Defendants unlawfully incentivized physicians by waiving copays and deductibles and paying illegal remuneration in the form of kickbacks for the purpose of procuring more physicians to order tests, which were ultimately submitted to Medicare, Medicaid, other government programs, and private insurance companies for reimbursements. Defendants also pay contractors a commission based on a percentage of the laboratory's revenue in exchange for the contractor arranging for and recommending physicians who order tests that are reimbursed by Medicare, Medicaid, and other government programs in violation of Cal. Ins. Code §1871.7(a). Defendants conspired together, and did so in order to submit claims for payment to insurance carriers in violation of Cal. Ins. Code §1871.7(a).

177. Because the claims submitted to medical insurers by Defendants were procured by runners, cappers, and steerers and other persons, these claims were false and fraudulent under the California Insurance Frauds Prevention Act.

178. This conduct was a substantial factor causing damages detailed herein.

SIXTH CAUSE OF ACTION

On Behalf of the State of California

California Insurance Frauds Prevention Act, Presenting or Causing to be Presented False or Fraudulent Claims for the Payment of An Injury Under A Contract of Insurance

Cal. Ins. Code § 1871.7(b); Cal. Pen. Code § 550(a)(1)

Against All Defendants

179. Plaintiffs incorporate by reference and reallege all of the allegations contained in paragraphs 1 through 169 of this Complaint as though fully set forth herein.

180. Defendants have all either knowingly presented or caused to be presented false and fraudulent claims for reimbursement of tests, or conspired to present or cause to be presented such false and fraudulent claims.

181. These claims were fraudulent because:

- Defendants knowingly sought and falsely represented that they were entitled to reimbursement for medically unreasonable and unnecessary tests.
- Defendants knowingly billed Medicare, Medicaid, other government programs, and private insurers for medically unnecessary and unreasonable tests.
- Defendants knowingly sought and falsely represented that they were entitled to reimbursement for tests that were procured by means of, or otherwise involved, the payment of illegal kickbacks.

182. Defendants either directly presented such false claims for payment to insurers, or caused such false claims to be presented.

183. This conduct was a substantial factor causing damages detailed herein.

/ / /

/ / /

/ / /

/ / /

/ / /

SEVENTH CAUSE OF ACTION

On Behalf of the State of California

California Insurance Frauds Prevention Act, Knowingly Preparing or Making Any Writing in Support of a False or Fraudulent Claim

Cal. Ins. Code § 1871.7(b); Cal. Pen. Code § 550(a)(5)

Against All Defendants

184. Plaintiffs incorporate by reference and reallege all of the allegations contained in paragraphs 1 through 174 of this Complaint as though fully set forth herein.

185. Defendants have all either knowingly prepared, made, or subscribed a writing with an intent to present or use it, or to allow it to be presented, in support of false and fraudulent claims for the reimbursement of tests performed on patients, or have aided, abetted, and solicited, or conspired to make, or subscribe such a writing.

186. These writings include bills for payment presented to insurance carriers for payment, and invoices prepared in support of such bills for payment. Such bills for payment constitute false or fraudulent claims because through those bills:

- Defendants knowingly sought and falsely represented that they were entitled to reimbursement for medically unreasonable and unnecessary tests.
- Defendants knowingly billed Medicare, Medicaid, other government programs, and private insurers for medically unnecessary and unreasonable tests.
- Defendants knowingly sought and falsely represented that they were entitled to reimbursement for tests that were procured by means of, or otherwise involved, the payment of illegal kickbacks.

187. Defendants either directly presented such false claims for payment to insurers, or caused such false claims to be presented.

188. This conduct was a substantial factor causing damages detailed herein.

/ / /

/ / /

/ / /

EIGHTH CAUSE OF ACTION

On Behalf of the State of California

California Insurance Frauds Prevention Act, Knowingly Making or Causing to be Made Any False or Fraudulent Claim for Payment of a Health Benefit

Cal. Ins. Code § 1871.7(b); Cal. Pen. Code § 550(a)(6)

Against All Defendants

189. Plaintiffs incorporate by reference and reallege all of the allegations contained in paragraphs 1 through 179 of this Complaint as though fully set forth herein.

190. Defendants have all either knowingly presented or caused to be presented false and fraudulent claims for reimbursement of tests performed on patients, or have aided, abetted, and solicited, or conspired to present or cause to be presented such false and fraudulent claims.

191. The claims were false or fraudulent because:

- Defendants knowingly sought and falsely represented that they were entitled to reimbursement for medically unreasonable and unnecessary tests.
- Defendants knowingly billed Medicare, Medicaid, other government programs, and private insurers for medically unnecessary and unreasonable tests
- Defendants knowingly sought and falsely represented that they were entitled to reimbursement for tests that were procured by means of, or otherwise involved, the payment of illegal kickbacks.

192. Defendants either directly presented such false claims for payment to insurers, or caused such false claims to be presented.

193. This conduct was a substantial factor causing damages detailed herein.

/ / /

/ / /

/ / /

/ / /

/ / /

/ / /

NINTH CAUSE OF ACTION

On Behalf of the State of California

California Insurance Frauds Prevention Act, Soliciting, Accepting, and Referring Business To or From an Individual or Entity That Intends to Violate Section 550 of the Penal Code or Section 1871.4 of the Insurance Code

Cal. Ins. Code § 1871.7(b); Cal. Pen. Code § 549

Against All Defendants

194. Plaintiffs incorporate by reference and reallege all of the allegations contained in paragraphs 1 through 184 of this Complaint as though fully set forth herein.

195. Defendants have solicited, accepted, or referred business to or from an entity or individual that intended to violate Section 550 of the Penal Code or Section 1871.4 of the Insurance Code.

196. The claims were false or fraudulent because:

- Defendants knowingly billed Medicare, Medicaid, other government programs, and private insurers for medically unnecessary and unreasonable tests.
- Defendants knowingly billed Medicare and private insurers for medically unnecessary and unreasonable tests.
- Defendants knowingly sought and falsely represented that they were entitled to reimbursement for tests that were procured by means of, or otherwise involved, the payment of illegal kickbacks.

197. Defendants either directly presented such false claims for payment to insurers, or caused such false claims to be presented.

198. This conduct was a substantial factor causing damages detailed herein.

/ / /

/ / /

/ / /

/ / /

/ / /

TENTH CAUSE OF ACTION

On Behalf of the Commonwealth of Massachusetts

Massachusetts False Claims Act, Presenting False Claims Massachusetts General Laws chapter 12, § 5B(1)

Against All Defendants

199. Plaintiffs incorporate by reference and reallege all of the allegations contained in paragraphs 1 through 189 of this Complaint as though fully set forth herein.

200. At all times relevant hereto, Defendants, and each of them, knowingly (as defined in Massachusetts General Laws chapter 12, section 5A) presented, or caused to be presented, claims for payment or approval in the form of invoices submitted to MassHealth that reflected prices higher than the maximum reimbursement rates allowed by law. Specifically, Defendants, and each of them, submitted or caused to be submitted invoices for payment of MassHealth covered clinical laboratory tests at amounts grossly in excess of the amounts contemplated by law, resulting in great financial loss to the Commonwealth.

201. Defendants' conduct violated Massachusetts General Laws chapter 12, section 5B(1), and was a substantial factor in causing the Commonwealth to sustain damages in an amount according to proof pursuant to Massachusetts General Laws chapter 12, section 5B.

ELEVENTH CAUSE OF ACTION

On Behalf of the Commonwealth of Massachusetts

Massachusetts False Claims Act, Making or Using False Records or Statements To Obtain Payment or Approval of False Claims Massachusetts General Laws chapter 12, § 5B(2)

Against All Defendants

202. Plaintiffs incorporate by reference and reallege all of the allegations contained in paragraphs 1 through 192 of this Complaint as though fully set forth herein.

203. At all times relevant hereto, Defendants, and each of them, knowingly (as defined in Massachusetts General Laws chapter 12, section 5A) made or used, or caused to be made or used, false records or statements to obtain payment or approval of false claims. Specifically, Defendants

billed the DHCFP at rates equal to or in excess of the maximum rates specified by the MassHealth rate schedule, rather than the discounted rates offered to others.

204. Defendants' conduct violated Massachusetts General Laws chapter 12, section 5B(2), and was a substantial factor in causing the Commonwealth to sustain damages in an amount according to proof pursuant to Massachusetts General Laws chapter 12, section 5B.

TWELFTH CAUSE OF ACTION

On Behalf of the Commonwealth of Massachusetts

Massachusetts False Claims Act, Retention of Proceeds Of Inadvertently Submitted False Claims Massachusetts General Laws chapter 12, § 5B(9)

Against All Defendants

205. Plaintiffs incorporate by reference and reallege all of the allegations contained in paragraphs 1 through 195 of this Complaint as though fully set forth herein.

206. Plaintiff is informed and believes, and on that basis alleges, that as to each claim for MassHealth reimbursement submitted for a test as to which the Defendant charged other clients less than it charged to DHCFP, each Defendant: (a) was a beneficiary of an inadvertent submission of a false claim to DHCFP; (b) subsequently discovered the falsity of the claim; (c) and failed to disclose the false claim to DHCFP within a reasonable time after discovery of the false claim. Specifically, each Defendant billed DHCFP at rates equal to or in excess of the maximum rates specified by the MassHealth rate schedule, rather than the discounted rates offered to others, and on discovering that it had done so, failed to promptly disclose the overcharge to DHCFP and make restitution therefor.

207. Defendants' conduct violated Massachusetts General Laws chapter 12, section 5B(9) and was a substantial factor in causing the Commonwealth to sustain damages in an amount according to proof pursuant to Massachusetts General Laws chapter 12, section 5B.

/ / /

/ / /

/ / /

/ / /

THIRTEENTH CAUSE OF ACTION

On Behalf of the State of Georgia

Georgia False Medicaid Claims Act, Presenting False Claims

OCGA § 49-4-168.1(a)(1)

Against All Defendants

208. Plaintiffs incorporate by reference and reallege all of the allegations contained in paragraphs 1 through 198 of this Complaint as though fully set forth herein.

209. At all times relevant hereto, Defendants, and each of them knowingly (as defined in OCGA § 49-4-168(2)) presented, or caused to be presented, claims for payment or approval in the form of invoices submitted to Medicaid that reflected prices higher than the maximum reimbursement rates allowed by law. Specifically, Defendants, and each of them, submitted or caused to be submitted invoices for payment in excess of the amounts contemplated by law, resulting in great financial loss to the State.

FOURTEENTH CAUSE OF ACTION

On Behalf of the State of Georgia

Georgia False Medicaid Claims Act, Making or Using False Records or Statements

OCGA § 49-4-168.1(a)(2)

Against All Defendants

210. Plaintiffs incorporate by reference and reallege all of the allegations contained in paragraphs 1 through 200 of this Complaint as though fully set forth herein.

211. At all times relevant hereto, Defendants, and each of them, knowingly (as defined in OCGA § 49-4-168(2)) made or used, or caused to be made or used, false records or statements to obtain payment or approval of false claims. Specifically, Defendant billed the Division at rates equal to or in excess of the maximum rates specified by the Medicaid rate schedule, rather than the discounted rates offered to others.

212. Defendants' conduct violated OCGA § 49-4-168.1(a)(2), and was a substantial factor in causing the State to sustain damages in an amount according to proof pursuant to OCGA § 49-4-168.1(a).

XI. PRAYER FOR RELIEF

WHEREFORE, Plaintiffs by and through Relator, pray judgment in its favor and against Defendants as follows:

213. Defendants' conduct violated the Federal False Claims Act, the California Insurance Frauds Prevention Act, the Georgia False Claims Act, and the Massachusetts False Claims Act, and was a substantial factor in causing the United States and the states of California, Georgia, and Massachusetts to sustain damages in an amount according to proof pursuant to the Federal False Claims Act, the California Insurance Frauds Prevention Act, the Georgia False Claims Act, and the Massachusetts False Claims Act . That judgment be entered in favor of plaintiffs UNITED STATES OF AMERICA, STATE OF CALIFORNIA, STATE OF GEORGIA, and THE COMMONWEALTH OF MASSACHUSETTS ex rel. STF, LLC, and against Defendants TRUE HEALTH DIAGNOSTICS, LLC, JEFFREY P. "BOOMER" CORNWELL, CHRIS GROTTENTHALER, CAROL NELLIS, SAM FILLINGANE, KEVIN CARRIER, CHARLES MAIMONE, according to proof, as follows:

a. On the **First Cause of Action** (Presenting False Claims (31 U.S.C. § 3729(a)(1)(A))) damages as provided by 31 U.S.C. § 3729(a)(1), in the amount of:

   i. Triple the amount of damages sustained by the Government;

   ii. Civil penalties of Eleven Thousand Dollars ($11,000.00) for each false claim;

   iii. Recovery of costs;

   iv. Pre- and post-judgment interest;

   v. Such other and further relief as the Court deems just and proper;

b. On the **Second Cause of Action** (False Claims Act; Making or Using False Records or Statements Material to Payment or Approval of False Claims (31 U.S.C. § 3729(a)(1)(B))) damages as provided by 31 U.S.C. § 3729(a)(1) in the amount of:

   i. Triple the amount of damages sustained by the Government;

   ii. Civil penalties of Eleven Thousand Dollars ($11,000.00) for each false claim;

   iii. Recovery of costs;

   iv. Pre- and post-judgment interest;

v. Such other and further relief as the Court deems just and proper;

c. On the **Third Cause of Action** (False Claims Act; Conspiracy to Commit Violations (31 U.S.C. § 3729(a)(1)(C))) damages as provided by 31 U.S.C. § 3729(a)(1) in the amount of:

i. Triple the amount of damages sustained by the Government;

ii. Civil penalties of Eleven Thousand Dollars ($11,000.00) for each false claim;

iii. Recovery of costs;

iv. Pre- and post-judgment interest;

v. Such other and further relief as the Court deems just and proper;

d. On the **Fourth Cause of Action** (False Claims Act, Retention of Proceeds to Which Not Entitled (31 U.S.C. § 3729(a)(1)(G))) damages as provided by 31 U.S.C. § 3729(a)(1) in the amount of:

i. Triple the amount of damages sustained by the Government;

ii. Civil penalties of Eleven Thousand Dollars ($11,000.00) for each false claim;

iii. Recovery of costs;

iv. Pre- and post-judgment interest;

v. Such other and further relief as the Court deems just and proper.

e. On the **Fifth, Sixth, Seventh, Eighth, and Ninth Causes of Action** (California Insurance Frauds Prevention Act §§ 1871.7(a) and (b) and California Penal Code §§550(a)(1); 550(a)(5); 550(a)(6) and 549) damages as provided by California Insurance Frauds Prevention Act §§ 1871.7, et seq., in the amount of:

i. Civil penalties of Eleven Thousand Dollars ($11,000) for each false and fraudulent claim submitted, presented or caused to be submitted or presented to an insurance company;

ii. Assessments of three-times the amount of each claim for compensation made by Defendants;

iii. Recovery of costs;

iv. Pre- and post-judgment interest;

v. Such other and further relief as the Court deems just and proper

f. On the **Tenth Cause of Action** (Massachusetts False Claims Act; Presentation of False Claims to Massachusetts (Massachusetts General Laws chapter 12, section 5B(1))), damages as provided by Massachusetts General Laws chapter 12, section 5B in the amount of:

i. Triple the amount of the Commonwealth's damages;

ii. Civil penalties of Eleven Thousand Dollars ($11,000.00) for each false claim;

iii. Recovery of costs, attorneys' fees and expenses;

iv. Such other and further relief as the Court deems just and proper;

g. On the **Eleventh Cause of Action** (Massachusetts False Claims Act; Causing False Records or Statements To Be Made or Used To Get False Claims Paid or Approved By Massachusetts (Massachusetts General Laws chapter 12, section 5B(2))), damages as provided by Massachusetts General Laws chapter 12, section 5B in the amount of:

i. Triple the amount of the Commonwealth's damages;

ii. Civil penalties of Eleven Thousand Dollars ($11,000.00) for each false claim;

iii. Recovery of costs, attorneys' fees and expenses;

iv. Such other and further relief as the Court deems just and proper.

h. On the **Twelfth Cause of Action** (Massachusetts False Claims Act; Retention of Proceeds Of Inadvertently Submitted False Claims (Massachusetts General Laws chapter 12, section 5B(9))) damages as provided by Massachusetts General Laws chapter 12, section 5B in the amount of:

i. Triple the amount of the State's damages;

ii. Civil penalties of Eleven Thousand Dollars ($11,000.00) for each false claim;

iii. Recovery of costs, attorneys' fees and expenses;

iv. Such other and further relief as the Court deems just and proper.

i. On the **Thirteenth Cause of Action** (Georgia False Medicaid Claims Act; Presentation of False Claims to Georgia (OCGA § 49-4-168.1(a)(1)), damages as provided by OCGA § 49-4-168.1(a) in the amount of:

i. Triple the amount of the State's damages;

ii. Civil penalties of Eleven Thousand Dollars ($11,000.00) for each false claim;

iii. Recovery of costs, attorneys' fees and expenses pursuant to OCGA § 49-4-168.2(i);

iv. Such other and further relief as the Court deems just and proper;

j. On the **Fourteenth Cause of Action** (Georgia False Medicaid Claims Act; Causing False Records or Statements To Be Made or Used To Get False Claims Paid or Approved By Georgia (OCGA § 49-4-168.1(a)(2)), damages as provided by OCGA § 49-4-168.1(a) in the amount of:

i. Triple the amount of the State's damages;

ii. Civil penalties of Eleven Thousand Dollars ($11,000.00) for each false claim;

iii. Recovery of costs, attorneys' fees and expenses pursuant to OCGA § 49-4-168.2(i);

iv. Such other and further relief as the Court deems just and proper.

/ / /

/ / /

/ / /

/ / /

/ / /

/ / /

/ / /

/ / /

/ / /

/ / /

/ / /

/ / /

/ / /

214. Further, Relator, on its own behalf, pursuant to 31 U.S.C. section 3730(d), California Insurance Frauds Prevention Act §§ 1871.7(g)(1)(A), and the False Claims Acts and applicable laws of California, Georgia, and Massachusetts requests that Relator receive such maximum amount as permitted by law, of the proceeds of this action or settlement of this action collected by the United States, California, Georgia, and/or Massachusetts plus an amount for reasonable expenses incurred, plus reasonable attorneys' fees and costs of this action. Relator requests that its percentage be based upon the total value recovered, including any amounts received from individuals or entities not parties to this action.

Respectfully Submitted,

Dated: May 30, 2018

COTCHETT, PITRE & McCARTHY, LLP
NIALL P. McCARTHY
JUSTIN T. BERGER
ERIC J. BUESCHER
MALLORY A. BARR

THE STEIDLEY LAW FIRM

By: _____
JEFFREY W. STEIDLEY

Attorneys for Relator STF, LLC

XII. DEMAND FOR JURY TRIAL

Relator STF, LLC hereby demands a jury trial on all issues so triable.

Respectfully Submitted,

Dated: May 30, 2018

COTCHETT, PITRE & McCARTHY, LLP
NIALL P. McCARTHY
JUSTIN T. BERGER
ERIC J. BUESCHER
MALLORY A. BARR

THE STEIDLEY LAW FIRM

By: _____
JEFFREY W. STEIDLEY

Attorneys for Relator STF, LLC